

Respiratory Therapy™

The Journal of Pulmonary Technique

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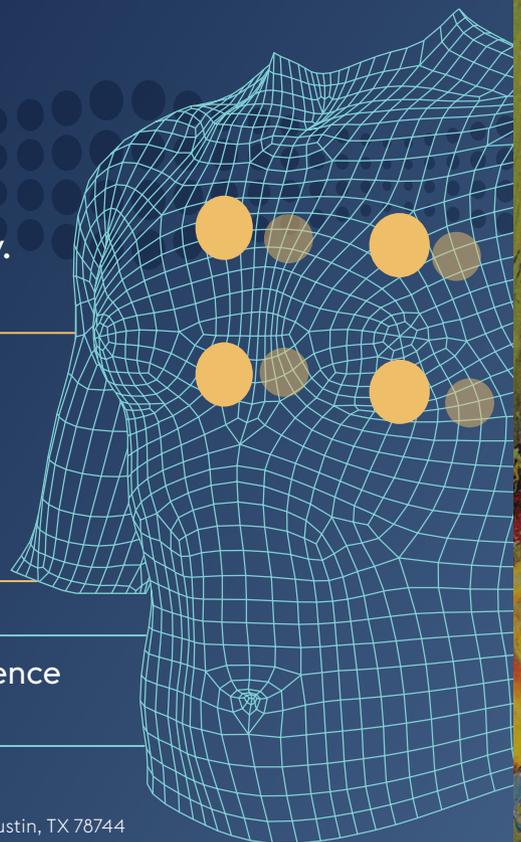
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Learn more about the clinical study on the mode of action of High Frequency Chest Wall Oscillation vests.

See inside for the clinical study, **Effect of High Frequency Chest Wall Oscillation Vests on Spirometry Measurements** (page 33) conducted by Thomas W. O'Brien, MD.

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1. Barto T, et al., Registry outcomes for HFCWO vest therapy in adult patients with bronchiectasis, Am Thor Soc Ann Meet, San Francisco, CA, May 2016, Poster P1496.

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Landmark Pulmonary Clinical Study Published in Respiratory Therapy

IRB-Approved Clinical Study demonstrates that compressor-style vests do not increase cephalad airflow bias in the lungs; FVC, FEV1 and FEF25-75% lung function scores showed statistically significant decreases in airflow during use of compressor-style vests

International Biophysics Corporation, a 26-year-old global medical device manufacturer based in Austin, Texas, has announced the publication of a clinical study on the mode of operation of High Frequency Chest Wall Oscillation (HFCWO) vests. The study, *Effect of High Frequency Chest Wall Oscillation Vests on Spirometry Measurements*, was published in Respiratory Therapy's online issue and will be featured in the next print issue scheduled for September. In addition, the abstract of the study will be published in Pediatric Pulmonology. A live presentation of the study will occur at this year's North American Cystic Fibrosis Conference in Denver on Thursday, October 18, 11:15 am-1:45 pm. HFCWO is a form of Airway Clearance Therapy for bronchial secretion clearance used in the treatment of Cystic Fibrosis, Bronchiectasis, Chronic Obstructive Pulmonary Disease (COPD), neuromuscular diseases and other disorders. It is estimated that over 5 million people in the United States may have Bronchiectasis. Despite the widespread use of HFCWO devices, little has been published regarding the operating principles of the technologies and the claims of increased cephalad airflow bias in the lungs as a mechanism of operation. Thomas W O'Brien, MD, Pulmonologist at Pulmonary Disease Specialists in Kissimmee, Florida and the study's Principal Investigator, explained its primary purpose. "In the past, manufacturers claimed that 'airflow bias' is the primary operating principle, but valid clinical evidence supporting that claim is lacking. We aimed to prospectively evaluate lung function scores using different types of HFCWO vests to evaluate the claims of airflow bias in the lungs." The prospective, single-center three-arm study enrolled 32 healthy subjects between February and March 2018. The trial was registered in ClinicalTrials.gov via the Protocol Registration System (PRS), completed under Institutional Review Board (IRB) approval, and published in Respiratory Therapy, the first study of its kind to measure airflow bias during use with HFCWO therapy. Each subject was assessed according to the American Thoracic Society's (ATS) guidelines for baseline lung function parameters. Included in these parameters are Forced Vital Capacity (FVC), Forced Expiratory Volume (FEV1), Peak Expiratory Flow (PEF) and Tidal Volume (TV). Each subject was fitted with two different types of HFCWO vests. One type was International Biophysics' AffloVest® mechanical oscillator-based device, and the other type was one of three compressor-based "air bladder" devices (The Vest®, SmartVest®, inCourage®).

Lung function tests were then performed on each subject, comparing each subject's baseline pulmonary lung function values without a vest against the values observed during use of an HFCWO vest. Dr O'Brien also said that, "Mechanical oscillatory action on the chest wall helps to loosen secretions, much like manual Chest Physical Therapy (CPT). This study was designed to investigate the effects of the application of mechanical oscillatory and compressor-based HFCWO vests during use on standard spirometry parameters. The results are very interesting and clinically relevant." The study found for the first time that the application of compressor-based HFCWO vests led to a significant decrease in FVC, FEV1 and FEF25-75% from baseline during use. In addition, the standard spirometry measurements collected in this study show no increase in PEF in any of the HFCWO vest groups and thus do not support the concept of HFCWO vest-induced cephalad airflow bias in the lungs as an operating principle of HFCWO vest therapy. Although both groups showed a decline in FEF25-75%, the compressor style group decrease in FEF25-75% was 3 times that of the AffloVest®. Observed David Shockley, International Biophysics' President and CEO, "This clinical study challenges the long-held belief that HFCWO vest-induced cephalad airflow bias correlates to effective airway clearance therapy. Manual Chest Physical Therapy (CPT) has always been considered the gold standard in mobilizing and clearing lung secretions. We engineered and developed the AffloVest to mimic hand CPT using our patented Direct Dynamic Oscillation™ technology that also provides the benefit of mobility and portability during use for the user. International Biophysics Corporation is a company with a strong 26-year history of developing and launching innovative and disruptive technologies. The company is focused on offering patients better outcomes through improved treatment therapies. Centered on a precision ISO 13485 certified, FDA registered quality-controlled manufacturing facility in Austin, Texas, International Biophysics continues to research and develop advanced solutions for physicians and patients.

The Benefits of BCV

BCV increases the safety of a patient that did not have a functioning pulse oximeter after paralysis. In a recent article from the American Journal of Emergency Medicine, it reports BCV can be used to oxygenate a paralysed patient during rapid sequence intubation (RSI), ultimately increasing safety when a patient does not have a functioning pulse oximeter. It concluded that BCV "may serve as a useful adjunct to RSI in high-risk situations." **BCV is safe, effective, and easy to apply means of ventilation that is available for hospital or home.** The United Hayek ventilators work using a unique Biphasic Cuirass Ventilation (BCV) technique. A negative pressure is generated within the chest cuirass, for inspiration or continuous inspiratory assistance, and applies a positive pressure within the cuirass inducing expiration. This positive expiratory pressure means that expiration is an active phase in the respiratory cycle this makes the Hayek RTX particularly efficient at CO2 clearance. *With over 300 publications to date, BCV is a very well proven method of ventilation.* BCV provides an efficient and effective method of non-invasive external ventilation and is a real alternative to traditional forms of ventilation.

- Mimics the natural physiology of spontaneous ventilation.
- Active expiratory phase.
- Full support with no risk with no risk of VAP, barotrauma or infection.
- Eat, drink and talk while fully supported.
- BCV can be used in place of BiPAP, CPAP (where underlying

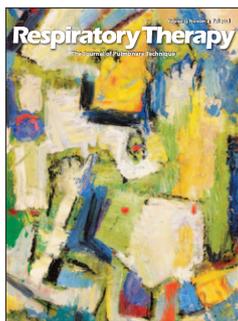


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OSA if not a factor), vest and cough assist type devices, and in many cases, invasive positive pressure ventilation.

Portable Oxygen Concentrator Makes Official Debut

CAIRE Inc., manufacturers of oxygen therapy devices including the AirSep, SeQual and HELIOS brands, announced the official debut of the new portable oxygen concentrator, the FreeStyle Comfort, at their global manufacturing headquarters and respiratory Center of Excellence in Georgia. Following a quiet, controlled launch in January with select CAIRE partners, the company is officially putting the spotlight on the new 5-pulse-setting model featuring an innovative comfort curve and weighing only 5 pounds. "We are proud to introduce the latest in a long line of leading oxygen therapy equipment. The FreeStyle Comfort blends together durability, clinical efficacy and comfort for its user. We remain focused on providing our DME/HME providers, clinicians and their patients the products and services they need to provide the best of care," said Earl Lawson, President of the BioMedical Group at Chart Industries, Inc. One of the major things users will notice on the FreeStyle Comfort is the shell of the device features a comfort curve that is designed to skim the natural curve of the body and make it truly a comfortable device to wear in comparison to other portable oxygen concentrators that come in oval and more square shapes that do not offer a contour. "Today's launch is the culmination of a lot of hard work and innovation," said George Coppola, CAIRE Director of Marketing. "Our team has taken the development of this project extremely personal from the technological aspects to ergonomics. We pushed ourselves on all of the details — Is it comfortable? Where is the center of gravity? Can it be worn with or without a bag? We ultimately want the oxygen user to live their life to the fullest and maximize their comfort as they do it." Operational via wall outlet (AC) power, motor vehicle (DC) power, or by rechargeable battery power, the device is designed for travel including its FAA approval for use on commercial air flights. The FreeStyle Comfort offers an easy-to-use interface with glow-in-the-dark buttons and LCD display screen that shows prescribed flow setting and remaining battery charge. User-replaceable battery packs come in two sizes, 8-cell and 16-cell, and can operate up to 4 and 8 hours, respectively, at pulse

setting 2, extending the user's time away from electrical power. The FreeStyle Comfort delivers up 1050 milliliters of oxygen per minute and is equipped with CAIRE's UltraSense technology, ensuring a pulse of oxygen is delivered quickly in the early stages of the breath, reducing skipped breaths. And, should a no-breath alarm occur, the device will deliver oxygen therapy rapidly at its current setting at a rate of 20 breaths per minute until this alarm condition has been resolved. The first smart portable oxygen concentrator, the FreeStyle Comfort comes with wireless connectivity capabilities for providers to periodically monitor location and usage through CAIRE's telehealth solution, CAIREview™ powered by SynsorMed. This helpful mobile application can provide a critical link between the patient and the provider, dedicated to supporting their respiratory health care needs. According to the National Heart, Lung and Blood Institute, approximately 12 million adults in the US are diagnosed with COPD, and there are an additional 12 million adults in the US who are thought to have undiagnosed COPD. Oxygen therapy is often prescribed for the treatment of COPD and to encourage its user to maintain an active lifestyle.

Company Announces Upgrades to Ventilators

ResMed, a global leader in cloud-connected respiratory care devices, announced key upgrades to its Astral life-support ventilators, including Optional AutoEPAP in iVAPS for U.S. patients, a high-demand therapy option. AutoEPAP (automatic expiratory positive airway pressure) automatically adjusts a patient's expiratory pressure in response to flow limitations or obstruction of the upper airway. AutoEPAP is now available in the United States, and already in use in other markets. It's an option when in Astral's iVAPS (intelligent Volume-Assured Pressure Support) mode that automatically adapts to a patient's changing pressure needs as their respiratory disease progresses. In addition to AutoEPAP, Astral users worldwide can now: **Easily change interfaces:** Patients can easily change between a mouthpiece and a full face, nasal or pillows mask from a single limb circuit; **customize program names:** Clinicians can now name programs on a patient's Astral device for fast, easy access. "These significant upgrades make Astral one of the most advanced life support ventilators on the market," said Richie McHale, president

of ResMed's Respiratory Care business. "It's already proven to stabilize ventilation in significantly fewer breaths than its leading competitor and today's innovations offer greater ease of use and even more peace of mind to patients across a wide range of respiratory diseases than ever before."

Glucose Hospital Meter System Approved for Testing

Nova Biomedical has announced that the StatStrip Glucose Hospital Meter System has been cleared by the US Food and Drug Administration (FDA) for fingerstick capillary testing with critically ill patients (K181043). StatStrip is the only glucose meter to earn this clearance and can now be used with arterial, venous, or capillary specimens from all patients including critically ill. The use of any other meter with critically ill patients is considered off label by the FDA and high complexity testing by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA). The FDA granted 510(k) clearance to StatStrip for capillary testing with critically ill patients following extensive prospective and retrospective studies performed at the Mayo Clinic in Rochester, MN, and Johns Hopkins Bayview Medical Center in Baltimore, MD. The submission data comprised 16,778 patients ranging from one month to 106 years old, all who were receiving intensive medical intervention/therapy in critical and intensive care settings including burn, cardiac, medical, orthopedic, neurological, and surgical. StatStrip's capillary results were equivalent to the arterial and venous plasma results measured on a central laboratory IDMS traceable reference method. The FDA clearance indicates that StatStrip is safe, effective, and reliable for use by CLIA-waived operators with critically ill patients. StatStrip's glucose technology is the primary reason for

the clinically acceptable agreement between the capillary and plasma glucose results. StatStrip is the only glucose technology for point-of-care testing (POCT) that measures and corrects for abnormal hematocrit and has no clinically significant interferences, which can lead to the mismanagement of critically ill patients. Capillary specimens are easy to collect and the least invasive glucose test at the point of care. Capillary specimens provide benefits such as rapid and actionable glucose results for immediate glycemic assessment and intervention, saving time for health care providers and improving safety and outcomes for patients. StatStrip's new capillary clearance eliminates the need for hospitals using StatStrip to define "critically ill." Hospitals using other glucose meters cannot test critically ill patients with those devices with any specimen type (arterial, capillary, or venous); such use is considered off label. In 2014, StatStrip became the only glucose meter to receive FDA clearance for arterial, venous, neonatal arterial, and neonatal heel stick use in all hospital and all professional healthcare settings including with critically ill patients (K132121), based upon a multicenter, four-year, prospective study conducted at five prestigious university medical centers. In that study, whole blood glucose measurements of 1,698 critically ill patients spanning 257 different medical conditions and over 8,000 medications were found to be equivalent to plasma glucose central laboratory IDMS traceable methods.

Firms Join Forces on Sleep Apnea Research

ResMed, a global leader in sleep apnea treatment and connected health solutions, and Verily, an Alphabet company, has announced their agreement to form a new joint venture. Combining ResMed's expertise in sleep apnea and Verily's

Sil.Flex™ TC Pad

Innovative pad stabilizes trach flange and absorbs pressure at stoma sites

Stoma sites may become sensitive or compromised due to constant pressure or movement of the tracheostomy tube and flange against tender tissue. The Sil.Flex™ TC Pad is designed to cushion the area between the flange and the stoma site, reducing movement and pressure at the site. The contoured surface of the Stoma Pad provides a stable, comfortable interface between the flange and the patient's neck.

Early use of the use of the TC Pad may assist in reducing irritation and tissue breakdown at the stoma site as well stabilizing the tracheostomy tube. Use of the TC Pad may decrease the air leak around the stoma site during trach weaning or during speech therapy by improving the seal between pad and stoma site.

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FEATURES

Available in two sizes, accommodating small infants through large adults

Contoured surface rests against the neck and reduces flange contact with stoma site

Hypo-allergenic, latex free, medical-grade silicone gel pad



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advanced health data analytics technologies, the U.S.-based joint venture will study the health and financial impacts of undiagnosed and untreated sleep apnea, and develop software solutions that enable healthcare providers to more efficiently identify, diagnose, treat and manage individuals with sleep apnea and other breathing related sleep disorders. Sleep apnea is a sleep breathing disorder that affects an estimated 54 million Americans (calculated based on a 16-country prevalence data study),¹ and is associated with heart disease, stroke, type 2 diabetes and other life-threatening conditions. Despite the condition's high prevalence and increasing public awareness, past research has shown that approximately 80 percent of individuals with obstructive sleep apnea are undiagnosed,² untreated and therefore unaware of their own risk and of the benefits that therapy could provide. "The vast majority of people with sleep apnea don't realize they have it, and therefore don't seek accessible, effective treatment to mitigate its effects and long-term health risks," said ResMed Chief Medical Officer Carlos M Nunez, MD. "The combined industry expertise, scalable infrastructure, and data analytics capabilities of ResMed and Verily can unlock meaningful ways to identify these individuals and support their journey to improved sleep, health and quality of life." "Approaching a widespread health problem like sleep apnea through collecting, organizing and activating health data is central to Verily's mission," said Jessica Mega, MD, MPH, Chief Medical and Scientific Officer at Verily. "By better identifying at-risk individuals as well as generating real-world evidence regarding the value and effectiveness of treatment, this collaboration has the potential to improve outcomes for millions of people living with sleep apnea, and potentially other related conditions." The joint venture, subject to customary closing conditions, including regulatory approvals, will operate as a separate venture from ResMed and Verily.

Device Wins Design Award

McArthur Medical Sales Inc. announced that the Flusso By Pass Adapter has been selected as the Silver Winner in the Nonsurgical Hospital Equipment category of the 20th Annual Medical Design Excellence Awards (MDEA) competition. Flusso by pass adapter can be used with passive or active humidity systems to prevent the disconnection of the patient from the mechanical ventilator during a circuit change, HME change or disconnection of patient for transport. Flusso was invented by Frank Fiorenza, a Registered Respiratory Therapist and Product Development Manager at McArthur Medical Sales Inc. The MDEAs are the medical technology industry's premier design competition committed to searching for the world's highest caliber medical devices, products, systems available on the market. The awards program celebrates the achievements of the medical device manufacturers, their suppliers, and the many people behind the scenes engineers, scientists, designers, and clinicians who are responsible for the cutting-edge products that are saving lives; improving patient healthcare; and transforming medtech one innovation at a time. "It was an honor to receive this award for our dedication to respiratory care" said Frank Fiorenza, "Flusso is now available to help patients around the world." Flusso™ was designed to improve the way we manage intubated patients, for more information visit www.flussobypass.com. The 2018 MDEA Juror Panel selected 42 exceptional finalists in nine medical technology product categories. Products were judged based on design and engineering innovation; function and user-related innovation; patient benefits; business benefits; and overall benefit to the healthcare system. Unlike other design competitions that

are merely styling contests, the MDEA jury is comprised of a balance of practicing doctors, nurses, and technicians alongside industrial designers, engineers, manufacturers, and human factors experts.

Switching to Bilevel PAP Saves 56% of Patients from Therapy Termination

A new study reveals that shifting patients who are struggling with adherence to positive airway pressure (PAP) therapy to a more advanced bilevel device in the first 90 days of treatment is an effective tool for achieving adherence in well more than half of such cases. This research, sponsored by ResMed, was presented this week at SLEEP, an annual joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society. Patients diagnosed with sleep apnea are usually prescribed a PAP device that provides either continuous (CPAP) or auto-adjusting (APAP) pressure. A bilevel device delivers two distinct pressures, one for inhalation and one for exhalation. Physicians may prescribe bilevel for patients who are pressure intolerant or have continued evidence of apnea at higher pressures. In this "Bilevel Rescue" study, ResMed compared 1,496 non-compliant patients (as defined by US Medicare guidelines) who switched to bilevel therapy and found that compliance was achieved by: 58.5 percent of patients who switched before day 60; 54.2 percent of patients who switched between days 60-90; and 56.8 percent of patients overall. "Finding the right mode of therapy made all the difference to those patients who are struggling with initial adherence to therapy," said ResMed Chief Medical Officer Carlos M. Nunez, MD. "This strongly suggests that bilevel devices provide a powerful alternative therapy that physicians and HMEs can utilize to help improve non-compliant patients' treatment experience and outcomes." *Compliance with Positive Airway Pressure Therapy after Switching From CPAP to Bilevel for Non-Compliant OSA Patients: A Big Data Analysis*: A PAP device telemonitoring database was queried for all patients initiated on CPAP or APAP (automatic positive airway pressure) therapy between January 1, 2015, and July 31, 2016, who were not Medicare compliant and switched to bilevel PAP therapy within the first 90 days of therapy. Anonymous PAP therapy data on all patients were compared before and after the switch. The objectives of this study were to compare average daily usage, adherence (percentage of days where usage was ≥4 hours), unintentional mask leak, and PAP efficacy (residual events) before and after switching to bilevel PAP therapy, as well as evaluating compliance using Medicare guidelines. An Institutional Review Board (IRB) reviewed this protocol and determined it to be exempt from IRB oversight.

The Benefits of Remote Patient Monitoring and Resupply Programs

Remote patient monitoring and resupply programs have been shown to improve patient adherence to positive airway pressure (PAP) therapy, according to two separate studies presented by ResMed at the ATS 2018 International Conference. In the first study, medXcloud, a ResMed-assembled group of healthcare key opinion leaders, examined de-identified data of more than 2.6 million US PAP users from ResMed's world-leading remote monitoring network, AirView. Using this big data approach, researchers observed excellent adherence among patients initiating PAP therapy: 75 percent achieved the CMS compliance threshold. This rate compares very favorably with that of non-cloud-connected PAP therapy and other chronic medical therapies — both around 50 percent. Plus, the large sample suggests that the findings are generalizable and likely to reflect

BETTER IS FASTER



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real-world clinical care. In a separate study of more than 100,000 well-matched PAP users, ResMed and collaborating researchers found that over a one-year period, those enrolled in a resupply program slept 5.6 hours on PAP each night, compared to 4.5 hours/night for those not enrolled (a 24 percent increase). Resupply patients were also significantly less likely to terminate PAP altogether, with a one-year termination rate probability of 16.1 percent for the resupply group, compared with 33.8 percent for the control group. *Real World PAP Adherence: Results from a Big Data Approach in More than Two Million Patients:* ResMed examined de-identified AirView database (ResMed Corp., USA) data in >2.6M U.S. sleep-disordered breathing (SDB) patients on PAP therapies (40.9% CPAP, 49.9% APAP, 9.2% Bilevel) to investigate 90-day adherence. To be included, patients were enrolled in the U.S. AirView database by their healthcare provider and used a single therapy mode to treat SDB available on the wirelessly connected AirSense or AirCurve 10 platforms. Data were extracted for adult patients (age >18 years) enrolled during the period 1 October 2014 to 31 October 2017, which contained at least one session with device usage ≥1 hour in the first 90 days. Researchers defined the primary outcome as adherence using CMS criteria. The study was reviewed by an Institutional Review Board (IRB) and deemed exempt from IRB oversight. The second study was *Positive Airway Pressure (PAP) Therapy Compliance on a Resupply Program: A Retrospective Analysis*. This study de-identified data from a patient billing database (Brightree) and de-identified device data from a telemonitoring database (AirView) were sent to a third-party independent statistician who provided the anonymized analyses and findings. Patients were included if they met the following criteria: initiation of PAP therapy between 1 July 2014 and 17 June 2016; achievement of CMS compliance; therapy management via telemonitoring (AirView; ResMed). Patients who started a resupply program (resupply group) were propensity matched 1:1 with patients who did not start a resupply program. The resupply program replenished a patient's PAP therapy equipment (mask systems and/or cushions). The primary endpoint was adherence, measured by average device usage hours per day, in the resupply versus control group. Secondary endpoints include other measures of adherence and device usage, and the rate of therapy termination (zero usage in the previous 30 days). The study protocol was reviewed by an Institutional Review Board and deemed exempt from IRB oversight.

Studies Highlight Combining Home Oxygen and Home Non-invasive Ventilation

ResMed announced the results of two clinical analyses conducted for the UK and US, demonstrating the cost effectiveness of combining home oxygen therapy and home non-invasive ventilation (NIV) therapy for patients with persistent hypercapnia following a life-threatening exacerbation of chronic obstructive pulmonary disease (COPD). The ResMed-backed Home Oxygen Therapy — Home Mechanical Ventilation (HOT-HMV) health economic studies, presented today at the ATS 2018 International Conference, build on earlier data demonstrating the clinical and cost effectiveness of HOT-HMV therapy (ie combining home oxygen therapy with home NIV), compared to treating with oxygen alone. The UK study found that HOT-HMV treatment reduced exacerbation frequency and 28-day hospital readmission. The US analysis found a 58.3 percent reduction in 30-day readmissions for HOT-HMV patients compared to those on home oxygen alone — and that HOT-HMV can actually save patients money while improving their

quality of life. *Cost-Effectiveness of Home Oxygen Therapy — Home Mechanical Ventilation (HOT-HMV) for the Treatment of Chronic Obstructive Pulmonary Disease (COPD) with Chronic Hypercapnic Respiratory Failure Following an Acute Exacerbation of COPD in the United Kingdom (UK):* This economic analysis was based on patient-level medical resource utilization (MRU) from the intention-to-treat analysis of an open-label parallel-group randomized clinical trial. Patients with a hospital admission due to an exacerbation of COPD requiring acute home mechanical ventilation (also known as non-invasive ventilation, or NIV) with persistent hypercapnia 2-4 weeks after resolution of respiratory acidosis were enrolled. Patients in the control arm were permitted to have NIV added to home oxygen therapy if the primary end-point (hospital readmission) was met and if pre-set safety criteria were breached (for example, persistent acidosis and inability to wean from NIV). The MRU analysis included patient-level evaluation of equipment (oxygen concentrator and NIV device, including maintenance and support), patient-reported medication, physician office visits, and hospital readmissions due to exacerbations. Trial data was used to develop an economic model from the UK National Health Service perspective. Costs were calculated by multiplying observed MRU by standard unit costs (2017£) and summed at the patient level. Quality-adjusted life years (QALYs) were measured based on patient health utilities calculated with UK coefficients and EuroQOL-5D data from the trial. One-way sensitivity analyses and a bootstrap analysis with 1,000 iterations were conducted. The US analysis was based on the UK study. Trial data was used to develop an economic model from the US payer perspective. Costs were calculated by multiplying observed MRU by standard unit costs (2017\$) and summed at the patient level. QALYs were measured based on patient health utilities calculated with US coefficients and EuroQOL-5D data from the trial. One-way sensitivity analyses and a bootstrap analysis with 1,000 iterations were conducted. Base-case incremental cost/QALYs gained was negative \$50,856.

Sleep Apnea Impacts Nearly 1 Billion Worldwide: Study

A new data analysis presented by ResMed at the ATS 2018 International Conference indicates that the prevalence of sleep apnea impacts more than 936 million people worldwide — nearly 10 times greater than previous estimates. The study “Global Prevalence of Obstructive Sleep Apnea (OSA)” was conducted by an international panel of leading researchers seeking to provide a clear scope of the impact of the chronic sleep-disordered breathing condition. The previous estimation of OSA prevalence (100 million) came from a 2007 World Health Organization study that used methods and data available at the time. By analyzing technology improvements in detecting OSA and underreported statistics from other areas of the world, this latest study depicts an impacted population significantly larger than previously identified. “The research and findings are a revelation in sleep apnea research and represent a vastly underreported major public health issue,” said Adam Benjafield, ResMed vice president of Medical Affairs and lead study researcher. “This new study demonstrates a need for expanded awareness around the diagnosis and treatment of OSA worldwide.” Sleep apnea is a chronic disease that causes people to stop breathing while they sleep. To avoid suffocation, the body is jolted by the brain to take a breath, typically without the person ever being aware. This cycle can repeat as many as hundreds of times a night, disrupting normal sleep patterns. Life-threatening conditions associated with OSA range from chronic daytime fatigue to heart disease, stroke, type 2 diabetes, depression, and more.

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Previous studies have suggested that undiagnosed sleep apnea costs nearly \$150 billion in the United States alone as a result of related lost productivity, motor vehicle accidents and workplace accidents — an economic impact that's likely much greater, given a higher prevalence total. **"This study should encourage physicians to talk with their patients about how sleep affects our overall health,"** said ResMed Chief Medical Officer Carlos M Nunez, MD. "It should also cause more people to ask themselves, 'Do I or my bed partner have this?' Those who have sleep apnea don't often realize they have it and, therefore, don't realize they can do something

to mitigate the resulting chronic fatigue or its more harmful long-term health risks. And sleep apnea isn't just a disease for older, overweight men, as once thought. It affects people of all ages, all ethnic and racial groups, all states of health, and is not gender specific. In fact, nearly half of newly diagnosed patients are female." In 2007, The World Health Organization (WHO) estimated more than 100 million people are affected by OSA, although they acknowledged that this figure was not based on robust data. The aim of this new study, *"Global Prevalence of Obstructive Sleep Apnea in Adults: Estimation Using Currently Available Data"* is to estimate the global adult prevalence of OSA.

Researchers identified 16 countries with published prevalence papers based on objective sleep studies and applied findings to areas previously under-quantified. After data review, estimates were extrapolated based on the global adult population aged 30—69 years. Prevalence statistics were applied to population numbers in each country based on the corresponding gender and body mass index (a key risk factor for OSA). OSA prevalence was estimated based on severity of the disease as measured by the apnea-hypopnea index. Convened by ResMed, the experts included representatives from North and South America, Europe, and Asia-Pacific.

Using endOclear® to Decrease Duration of Mechanical Ventilation

New study results are shedding light on how to decrease the duration of mechanical ventilation by using the endOclear® Restore™ device. The study authors are Ruth Karales and Vanessa Nonato, who work in Respiratory Care at Rush-Copley Medical Center in Aurora, IL. "During mechanical ventilation (MV), management of the critical patient can be a challenge in the Intensive Care Unit (ICU)," they wrote. "Complications include an increased amount of secretions adhering to the

endotracheal tube (ETT), which causes higher Peak Inspiratory Pressures (PIP) and Airway Resistance (RAW), making it difficult for patients to tolerate weaning from MV. ETT suctioning can be ineffective, leaving residual biofilm. The presence of biofilm may cause increased airway resistance and lead to longer duration of MV. The endOclear® Restore™ device purpose is to remove ETT secretions quickly and efficiently." The authors wrote that the objective of the study was to determine any benefits of the endOclear® Restore™ device to minimize biofilm formation, maintain airway patency, and decrease ventilation days. They conducted an IRB exempt, 2-year retrospective, observational

single center study to evaluate the efficacy of cleaning the ETT with endOclear® Restore™ after ETT suctioning and oral care has been completed. Ventilation day data was collected prior to using endOclear® on 374 subjects and post data on 336 subjects. "Subjects were admitted into our adult Medical/Surgical/Neuro ICU, intubated with an ETT, and mechanically ventilated," the study authors wrote. "Exclusion criteria included patients admitted for coronary artery bypass grafting, valve replacement, tracheostomy, and patients younger than 18 years of age. The measurements obtained before and after cleaning the ETT were PIP (362 observations) and Raw (352 observations). The

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paired t-Test was used to compare sample means.” According to the study report, data from this 2-year study revealed that the average duration of MV decreased from 2.85 to 2.42 days (0.43 ± 1.58 , $p < 0.01$), PIP was decreased from 26.2 to 24.9 cmH₂O (1.3 ± 3.9 , $p < 0.01$) and RAW was decreased from 17.3 to 15.8 cmH₂O/L/sec (1.5 ± 4.2 , $p < 0.01$) with the use of endOclear® device. Data is presented as mean \pm SD. The report concludes that “this study revealed that cleaning the ETT using the endOclear® Restore™ device, after ETT suctioning and oral care had already been completed, significantly reduced the average duration of MV. The removal of adherent secretions/residual biofilm also dramatically decreased PIP and RAW and assisted in decreasing the work of breathing.”

New Diffuser Vent Elbow Shushes CPAP Noise

ResMed has introduced the QuietAir diffuser vent elbow for its latest continuous positive airway pressure (CPAP) full face masks: AirFit F20 with silicone cushion and AirTouch F20 with memory foam cushion. QuietAir reduces noise by 89 percent and produces a 70 percent gentler exhaled airflow, compared to ResMed’s previous design, allowing for a quiet, uninterrupted night of sleep and mitigating two barriers to therapy compliance: noise and bed partner comfort. “With this technology, our full face masks’ noise levels are well below ambient noise in the bedroom,” said ResMed CEO Mick Farrell. “We are providing patients and their bed partners with the peace and quiet they deserve for better sleep.” QuietAir is the latest innovation to ResMed’s line of AirFit and AirTouch products: AirTouch F20 with UltraSoft memory foam, creating a personalized fit with a uniquely soft and breathable seal, and fitting 98 percent of patients; and AirFit F20 and AirFit N20 nasal mask, to enhance facial comfort and fit, fitting 97 and 99 percent of patients, respectively, regardless of facial structure, gender or age. All three masks complement ResMed’s suite of cloud-connected PAP devices: Air10 bedside machines and AirMini, the world’s smallest PAP device. Remote and self-monitoring, enabled by cloud connectivity, is proven to help improve patients adherence and clinicians’ business efficiencies. QuietAir diffuser vents for AirFit F20 and AirTouch F20 masks are now available in the Americas, EMEA and Asia-Pacific. For more information, contact your ResMed sales representative.

Patients Being Pushed Into Unsafe Tracheostomies

Alarms are being raised about the dangers of tracheostomies. A quick search on Google describes it as “*Tracheotomy, or tracheostomy, is a surgical procedure which consists of making an incision on the anterior aspect of the neck and opening a direct airway through an incision in the trachea.*” Notrach, an organization that specializes in helping patients seek alternatives to this potentially dangerous procedure, believes that the risks for tracheostomies are too great. The patient may need help breathing, be it for the long, or short term. “Have a tracheostomy.” How simple it sounds. But it is potentially seriously harmful. Patients are consenting to this procedure in their thousands across North America. However, the procedure may not be explained to them in the detail it should be. Possibly, neither are potential alternative options which could mean many of these patients wouldn’t have to have one. A small sample of the complications includes death, infections, bleeding, permanent damage to vocal cords, damage to the esophagus, air trapping (causing a life-threatening condition) and the list goes on. Yet thousands upon thousands of patients are consenting to this sometimes life-saving procedure. The key word here is *sometimes*. In so many cases, it could have, or should have

never been performed in the first place. The consent forms for these procedures are lengthy and varied. Why, one may ask, are these tracheostomies performed so often then? Sometimes the procedure is the only option the patient actually has. Often, however, that simply isn’t the case. Doctors today are far too ready and eager to perform these procedures. It has simply become routine. For some medical establishments, the fees can be upwards of \$250,000. It makes money. The past decade has seen a substantial increase in tracheostomies. In that same decade, so have the payments for compensation relating to these procedures. Most payouts are in the millions. Rarely will the doctors who convince their patients that this is the only option for them explain that other options might work for them. Non-invasive ventilation has come a long way in the last decade. There are two types currently available, Mask based ventilation, and Biphasic Cuirass Ventilation. It could well be that one or the other has failed, and the physician will then jump straight to a tracheostomy. The fact is, that very often, where one method has failed, the other could well work. Jumping straight to a tracheostomy without at least trying both options is like amputating one’s hand because it got infected. It’s like saying, one antibiotic was tried and it didn’t work, so we won’t bother to try another. Amputate! By jumping to a tracheostomy, without trying everything possible to avoid it — at the very least both forms of ventilation, (mask based, and Biphasic Cuirass Ventilation) the door can be left wide open to a claim of a particularly costly case of medical negligence. Gary Mefford of Hayek Medical, a device manufacturer that specializes in Biphasic Cuirass Ventilation, commented, “**We see this all too often. Patients are being pushed into it [a tracheostomy]. They simply are not being given the chance to avoid it. We have helped thousands upon thousands of patients worldwide. It’s proven. Case after case after case, it’s just unbelievable.**” The aftercare costs often run into millions. Infections which are incredibly common costs huge amounts of money to treat. Health insurance companies have started to question whether they should pay for these costs if the procedure could have been avoided in the first place. Perhaps when the payouts for negligence outweigh the amount earned by these procedures, the rules about when these procedures are appropriate will change.

Respiratory Device Company Acquired

Vyaire Medical, a global leader in respiratory care, announced that it has acquired Acutronic Medical Systems and, separately, entered into a definitive agreement to acquire imtmedical. Acutronic, a Switzerland and Germany-based leader in the design and manufacture of neonatal ventilation equipment, is globally recognized for its innovative ventilation solutions designed for both neonatal and pediatric intensive care units. imtmedical, based in Switzerland, is a developer, manufacturer and distributor of acute care mechanical ventilation products utilized in acute care centers, long-term care facilities, home healthcare as well as the emergency services and transport markets. The imtmedical transaction, which is subject to customary regulatory and other approvals, is expected to close in the second quarter. The Acutronic and imtmedical acquisitions immediately enhance Vyaire Medical’s product offering, complementing investments made by the Company through internal development programs. In combination, these investments have allowed Vyaire Medical to completely renew its ventilation portfolio within the past 18 months. Dave Mowry, Vyaire Medical’s President and Chief Executive Officer, said, “The transactions we are announcing today, along with our own internal development efforts, underscore our commitment to positioning Vyaire Medical as a



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global respiratory care leader. Our acquisition of Acutronic and imtmedical immediately enhance our product portfolio, expand intellectual capital and broaden our technological capabilities; all of which will accelerate Vyair Medical's growth. We could not be more excited about taking these amazing products, in combination with our own, to market to advance our mission of improving patient outcomes and providing increased value to our customers." Vyair Medical also announced today that funds advised by Apax Partners (the "Apax Funds") have completed their purchase of Becton, Dickinson & Company's remaining stake in the Company. Vyair Medical is now an independent, standalone company owned by the Apax Funds.

High-Flow Oxygen Improves Infant Bronchiolitis Outcomes

High-flow oxygen therapy was associated with improved outcomes among hospitalized infants with bronchiolitis treated outside intensive care units (ICUs) in a multicenter, randomized trial. Compared with infants treated with standard oxygen therapy, roughly half as many infants in the high-flow oxygen group required escalation of care (12% versus 23%), and there was no significant difference between the two groups in the incidence of adverse events. Bronchiolitis is the most common reason for hospital admission among infants worldwide, and in the US it is responsible for an annual \$1.7 billion in hospital costs. High-flow oxygen therapy is increasingly being used outside the ICU to provide respiratory support for infants, children, and adults with respiratory diseases. The new study, published online in the *New England Journal of Medicine*, is among the first to examine the treatment's safety and efficacy outside the ICU in infants with bronchiolitis, said the study's senior researcher, Andreas Schibler, MD, of the University of Queensland in South Brisbane, Australia.

Running with COPD

A Nonin wearable device is helping one athlete keep moving despite chronic obstructive pulmonary disease (COPD). Imagine breathing through a straw, and then running a marathon with this lung capacity; it doesn't sound fun, let alone possible, does it? Russell Winwood was diagnosed with COPD in 2011 and shortly after completed his first full ironman race in 2012. Based in Australia, Russell is an avid cyclist, marathon runner and one inspiring individual. He lives by the four pillars of COPD; knowledge, medication, nutrition and exercise, and will be traveling to the United States to race in the Boston Marathon. Russell will utilize the WristOx 3150 device to track his oxygen saturation levels and heart rate, as well as a Garmin to track his strides and distance. Russell trains four times a week, mostly running but incorporates stretching and strengthening routines as well. He is a leader in advocating for COPD patients to live a healthy happy life, and he is proof that it is possible and beneficial to stay active with COPD. The Boston Marathon is third on Russell's bucket list for racing. He has completed one in New York and London, and plans to race in Tokyo, Berlin and Chicago as well. He also has aspirations for the Race Across America in 2020. This extensive cycling race starts in Santa Monica and spans 3,000 miles to end in Annapolis, Maryland. Along this route, the cyclists climb 175,000 feet as they cross twelve states. Due to the high altitudes, an oxygen backpack will be necessary for Russell during this race which is different from his usual routine. He is typically able to race without the help of oxygen at moderate altitudes. Russell is a major inspiration to many individuals, with and without COPD. He mentored a woman in London helping her train for a marathon, and has

motivated many to be active and enjoy life to the fullest. Russell stressed the importance of a durable, wearable device to monitor his oxygen levels while racing. Learn more about Nonin oximetry and the WristOx 3150 on the company's website.

Therapy Hand Puppet Developed

Passy Muir has announced a new addition to its family of pediatric educational products. Featuring a pediatric tube and Passy Muir Valve for demonstration and education, the new Toby Tracheapuppet plush therapy hand puppet provides therapists and caregivers with a lighthearted method to introduce children to tracheostomy and the Passy Muir Valve. Perfect for interaction with young patients, the Toby Tracheapuppet facilitates vocalization and enhances therapeutic activities. For more information, or to purchase, visit www.passymuir.com.

Patent Clearance Approved

International Biophysics Corporation, a global medical device manufacturer based in Austin, Texas, announced two new patents have been issued from the United States Patent and Trademark Office (USPTO) for the company's AffloVest High Frequency Chest Wall Oscillation (HFCWO) vest. The patents, one for clearing a biological airway including a self-contained portable positionable oscillating motor array (9,895,287), and the second for (9,907,725) were issued February 20th and March 6th, 2018, respectively. International Biophysics founder and Chief Executive Officer, H David Shockley said, "**The issue of these two patents reaffirms our leadership in the introduction of innovative, effective treatment therapies. We pioneered mechanical oscillation airway clearance therapy for patients with severe respiratory diseases such as bronchiectasis, cystic fibrosis, neuromuscular diseases, and other respiratory conditions.**" The AffloVest is battery operated and uses Direct Dynamic Oscillation technology that closely mimics hand Chest Physical Therapy (CPT), which is considered the gold standard in mobilizing and clearing lung secretions. The technology allows for full freedom of mobility during patient treatment. The AffloVest features eight built-in oscillating modules that are anatomically positioned to target the lobes of the lung. Added Mr. Shockley, "We believe that our mechanical oscillation technology offers patients a more modern and patient friendly airway clearance therapy than the older style air bladder technology. We anticipate several more patents on our technology in the coming months."

New Anatomical Teaching Model Developed

Passy-Muir, Inc. has announced a new addition to its line of anatomical teaching models. Tracheostomy Pediatric Airway Model (P.A.M.) is designed for use by healthcare practitioners to educate students, families, patients, and clinicians about tracheostomy in the pediatric airway and the proper application of the Passy Muir Valve. Conveniently sized, Tracheostomy P.A.M. is designed to illustrate the approximate anatomy of a toddler (ages 2-4). Consistent with the anatomy of a toddler, P.A.M.'s epiglottis and vocal folds are represented in a higher position than in adults, the vocal folds are displayed in an anterior slanted position, and P.A.M.'s soft palate and tongue are larger in relation to the total size of the oral cavity. P.A.M. is packaged with helpful educational accessories to enable clinicians to provide a wide variety of education related to tracheostomy. The kit includes three demonstration Passy Muir Valves, a cuffed tracheostomy tube, and a syringe for cuff deflation. The kit allows for education and practice related to use of a speaking valve. A nasogastric tube is provided for the



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Patient Monitoring System Receives FDA Clearance

Getinge, a leading global provider of innovative medical technology, announced that the US Food and Drug Administration (FDA) has granted 510(k) clearance to its PulsioFlex Monitoring System and PiCCO Module. The PulsioFlex Monitoring System, from Getinge's Maquet brand, is a diagnostic aid used to measure and monitor blood pressure and cardiopulmonary, circulatory and organ function variables in patients in intensive care units (ICUs). The accompanying PiCCO Module is used for hemodynamic management of critically ill patients. It provides cardiac output measurement continuously based on pulse contour analysis and intermittently through transpulmonary thermodilution technique. "We plan to launch the PulsioFlex Monitoring System and PiCCO Module in the United States later this month. This will expand the portfolio of ICU solutions that we offer medical centers through our Advanced Patient Monitoring Business Area," said Greg Master, President, Acute Care Therapies USA, at Getinge. **"With FDA clearance of this advanced bedside monitoring system, we now have our own advanced hemodynamic patient monitoring system to offer hospitals to help their staff make more informed clinical decisions and provide high-quality care for critically ill patients. Until now, the PiCCO Module was available only for use with patient monitoring systems from GE Healthcare and Philips Medical Systems."** The PulsioFlex Monitoring System is a flexible platform for advanced hemodynamic monitoring that can be adapted to each patient's individual needs at any time. It also can be configured to support HIPAA compliance. The PulsioFlex Monitoring System has a modular setup that easily allows for future technology integration. Additionally, with the PulsioFlex monitor, the number of PiCCO parameters has been expanded by four — from nine to 13. Two of the additional parameters allow for expanded assessment of pulmonary edema beyond the extravascular lung water index (ELWI) parameter, including 1) pulmonary Vascular Permeability Index (PVPI) — Distinguishes between cardiogenic and permeability caused pulmonary edema, and 2) intrathoracic Blood Volume (ITBV) — Shown to be consistently 25 percent higher than Global End-Diastolic Volume in a clinical study using double-indicator dilution technology to measure ITBV and extravascular lung water (EVLW). Two of the additional PiCCO parameters expand capabilities for contractility monitoring: Global Ejection Fraction (GEF) — Offers a complete picture of the overall cardiac contractility; and cardiac Power Output/ Cardiac Power Index (CPO/CPI) — Shown in clinical studies to be the strongest independent predictor of hospital mortality in patients with cardiogenic shock. PulsioFlex includes OrganView, a novel graphical overview that uses a traffic light system to identify out-of-range values, and three different calculated volume test methods — Fluid Challenge, Passive Leg Raising and End Expiratory Occlusion — to help determine the patient's fluid responsiveness. The PulsioFlex monitoring system allows real-time dynamic monitoring with a dedicated PiCCO module, which is the only system in the U.S. today that continuously measures

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cardiac and pulmonary values such as CPI, ELWI and GEDI for the critically ill patient.

Air Pollution Tied to Low-Birth-Weight Risk

Air pollution, but not traffic noise, appears to be linked to an increased risk of having low-birth-weight babies, reports a new study from the UK. Previous studies have tied road traffic air pollution to low birth weight. Road traffic produces noise as well as pollution, but studies of noise pollution have had conflicting results, say the authors. “We know that noise is associated with adverse health effects, eg sleep disruption, increased blood pressure, and cardiovascular disease, so it could plausibly have an impact on mothers’ health in pregnancy and the health of unborn babies,” study leader Dr Rachel Smith at the School of Public Health of the Imperial College said. Smith’s team wanted to investigate the effect of exposures to both traffic-related air and noise pollution during pregnancy on babies’ birth weight. “We found increased risk of babies being born with low birth weight or small for gestational age, at term, to mothers with higher exposure to air pollution from road traffic during pregnancy. We did not see an independent effect of road traffic noise on birth weight,” she said. Smith and colleagues used national birth registers to identify over 540,000 live, single, full-term births occurring in the Greater London area between 2006 and 2010. Specifically, the study team was interested in low birth weight (<5.5 pounds) and being born small for gestational age. Mothers’ home addresses at the time of birth were used to estimate the average monthly exposure to traffic-related pollutants including nitrogen dioxide, nitrogen oxides, and fine particulate matter, or PM_{2.5}. The researchers also estimated average day and night-time road traffic noise levels. Increases in traffic-related air pollutants, especially PM_{2.5}, were associated with 2% to 6% increased odds of having a low birth weight baby and about 1% to 3% increased odds of a baby being small for gestational age, even after taking road traffic noise into account. The risk associated with air pollution should be considered in context, ie the size of the effect of air pollution on an individual baby’s birth weight is relatively small compared to the well-recognized effect of smoking, said Smith. “However, at the population level the impact could be large, because collectively more women are exposed to air pollution than are exposed to smoking during pregnancy,” she said. There is a limit to what individuals can do to reduce their exposure to air pollution because making major changes to lifestyle, travel or where they live is just not feasible for the vast majority of people. Improving air quality and reducing air pollution in our towns and cities, and thus reducing health impacts of air pollution, requires action by policymakers, said Smith. The study “should increase awareness that prenatal exposure to small particle air pollution is detrimental to the unborn child,” Sarah Stock and her colleague wrote. Stock, a researcher at the University of Edinburgh Queen’s Medical Research Institute in Edinburgh, UK, said air pollution from traffic is well known to be detrimental to child and adult health. “**This study provides further evidence that air pollution from traffic is also harmful to unborn babies. However, it shows that traffic noise is unlikely to be related to low birth weight in babies.**” Stock, who was not involved in the study said. Pollution should be high on agendas at a local and national level, with pollution control integrated into development planning, said Stock. “Key initiatives include enforcing emission control technologies in motor vehicles; ensuring easy access to affordable and efficient public transport; encouraging walking and cycling; and mandating clean air zones,” she said. Unfortunately, women have few options to reduce their risk on

a personal level, said Stock. “Avoiding air pollution is difficult, and we have no evidence that lifestyle measures, or wearing protective masks actually reduces chronic exposure to harmful pollutants. We do know avoiding exposure to tobacco smoke is really important. More research in this area is needed to find out the best ways for women to reduce their risk,” she said.

OSA May Increase Risk of Atrial Fibrillation

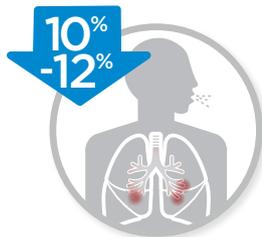
Obstructive Sleep Apnea (OSA) may increase the risk of developing atrial fibrillation (AF), according to new research presented at the ATS 2017 International Conference. OSA is characterized by repetitive episodes of shallow or paused breathing during sleep that lead to a drop in blood oxygen level and disrupted sleep. AF is one of the most common cardiac arrhythmias characterized by a rapid and irregular heartbeat that can lead to stroke and related heart problems. “There is strong biologic plausibility that obstructive sleep apnea may increase the risk of developing atrial fibrillation through a number of mechanisms,” said lead author Tetyana Kendzerska, MD, PhD, assistant professor of medicine at the University of Ottawa in Canada. “There is emerging evidence from animals and smaller studies in humans that OSA may increase the chances of developing AF through oxidative stress, increased sympathetic activity, metabolic abnormalities, endothelial dysfunction and cardiac stretch from intrathoracic pressure swings.” Researchers in Canada reviewed the records of 8,256 adults (average age 47) referred with suspected OSA, but free of any physician-diagnosed heart rate abnormalities, including AF at baseline. Participants were followed for up to 13 years. During that time, 173 developed AF resulting in hospitalization. Before controlling for established risk factors for AF, the researchers found that measures of OSA severity such as the number of times an individual partially or completely stopped breathing per hour of sleep and sleep time spent with oxygen saturation lower than normal (< 90 percent) were significant predictors of AF. Those who developed AF were more likely to be older, current or former smokers and have a high level of comorbidities. After adjusting for these and other known risk factors, the authors found that oxygen desaturation in sleep, but not the number of times an individual stops breathing, remained a significant predictor of AF hospitalizations. They also found the association between oxygen desaturation and AF hospitalization was stronger in women than men.

Adult Survivors of Preterm Birth Have Smaller Airways

The airways of adult survivors of preterm birth are smaller than those of their peers born full-term, which may help to explain their worse lung function, according to findings. Airway obstruction at rest is a “hallmark finding” in adults who had been born prematurely, Dr Joseph W Duke of Northern Arizona University in Flagstaff, who helped conduct the study, noted. On average, he added, premature birth is associated with a 20% to 30% reduction in lung function, with expiratory flow limitation (EFL) and reduced inspiratory volume during exercise. Dr Duke and his team used dysanapsis ratio (DR), an indirect measure that accounts for maximal flow, static recoil and vital capacity, to compare airway size in three groups of adults (mean age, 22 years): 14 who had been born at least eight weeks premature and had bronchopulmonary dysplasia (BPD), 21 born at least 8 weeks premature without BPD, and 24 term-born controls matched by age, sex and height. DR was 0.16 for the preterm adults without BPD, 0.10 for the BPD group, and 0.22 for the controls. DR correlated significantly with both peak expiratory airflow at rest ($r=0.42$) and expiratory flow limitation during

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© 2018 Monaghan Medical Corporation. ¹ Burudpakdee et al. Pulmonary Therapy 2017;3(2):283-296. ² Study Summary - AEROCHAMBER® brand of VHC.

exercise ($r=0.60$). The researchers used two different equations to measure DR, with consistent results: DR was significantly smaller for the preterm adults with or without BPD than for the controls, and those with BPD had significantly smaller DR than those without BPD. Given the findings, standard treatments for asthma and chronic obstructive pulmonary disease, which work by dilating the airways, may not be effective in these patients, Dr Duke noted. “We need to do some studies looking at these traditional medicines to reverse airflow obstruction and see what effect, if any, they have on adult survivors of preterm birth,” he said. He and his colleagues conclude: “The data in the present study suggest that smaller than normal airways explain, at least in part, the lower expiratory airflow rate in PRE (ie, without BPD) and BPD. The present findings add important information to our understanding of the cardiopulmonary physiology of PRE and BPD.”

Inhaled Budesonide May Yield Mixed Results in Premature Infants

Inhaled-glucocorticoid therapy does not appear to boost the longer-term risk of neurodevelopmental disability in extremely premature infants, but might increase mortality, according to a randomized controlled trial. “Thanks to the new study results, neonatologists can now make informed decisions regarding the use of inhaled glucocorticoids for the prevention of” bronchopulmonary dysplasia (BPD), chief author Dr Dirk Bassler, chief of neonatology at University Hospital Zurich said. “When making this decision, they need to carefully balance the risks of potentially increased mortality owing to early inhaled corticosteroids against those of decreased rates of BPD with no effect on neurodevelopment in survivors at 2 years of age.” BPD itself is the most common chronic complication of extremely preterm birth. It is associated with higher mortality, growth failure, neurodevelopmental delay and both chronic respiratory and cardiovascular impairment. It can be prevented with systemic glucocorticoids, but those carry a higher risk of neurodevelopmental impairment such as cerebral palsy, and intestinal perforation. So doctors often try inhaled glucocorticoids. “**Despite much study and progress in neonatology in recent years and some modest improvements in survival, both the incidence and severity of BPD have not changed much. To this day, approximately half of the infants born with a gestational age of less than 28 weeks suffer from BPD,**” Dr Bassler said. The popularity of glucocorticoid treatment varies widely. It was estimated a few years ago that it was prescribed for about 25% of premature infants in the United States versus about 70% in Japan. The latest findings, reported in *The New England Journal of Medicine*, are a follow-up to the group’s 2015 study in the *Journal*, which found that while inhaled budesonide lowered the dysplasia risk, it elevated the mortality rate. The new work evaluated data on 629 babies randomly assigned to placebo or budesonide at a corrected age of 18 to 22 months. All were at a gestational age of at least 23 weeks and less than 28 weeks at the time therapy began. In the trial, done at 40 centers in nine countries, the budesonide babies received 400 micrograms of the inhaled drug every 12 hours, with the daily dose reduced to 200 micrograms from day 15 until the babies didn’t need respiratory support. Drug treatment ended at 32 weeks. The rate of neurodevelopmental disability—a composite of cognitive delay, deafness, blindness or cerebral palsy—was 48.1% among the 308 budesonide recipients and 51.4% among the 321 who got placebo ($P=0.40$). The Bassler team also found no evidence that individual elements of that composite scale were affected by inhaled

budesonide therapy. Budesonide recipients were more likely to die during the study (19.9% vs. 14.5%, $P=0.04$). “This is unexpected,” Dr Bassler said, and “there is no biologically plausible hypothesis to explain the seeming excess of deaths in treated infants, and the causes of death in our study did not differ considerably between the groups. The mortality findings may be attributed to chance, but we can’t be sure about this assumption.” He said the results need to be seen in the context of other studies. “**There are now updated meta-analyses including our short-term outcomes that address the use of inhaled glucocorticoids as compared with placebo or no intervention,**” Dr Bassler said. “All updated systematic reviews and meta-analyses found a modest, but significant reduction in the composite outcome of death or BPD at 36 weeks. In these updated meta-analyses, inhaled glucocorticoids were associated with a significant reduction in BPD with no effect on mortality.”

Precise Measurements for a Small Price

imtmedical has launched its latest gas flow and pressure analyser. CITREX H3 is the latest gas flow and pressure gauge from imtmedical. The state-of-the-art device was developed as an easy to operate entry-level model with only the key features for verifying medical devices at an unbeatable price. CITREX H3 measures gas flow and pressure in the bidirectional flow channel. The accuracy of the flow measurements is $\pm 2\%$. CITREX H3’s wide measuring range of ± 300 l/min allows testing of various medical devices such as ICU and home care ventilators. With the CITREX H3, operators can measure the 16 most important ventilation parameters including: flow, pressure, volume, PEEP, and gas temperature. 5 different gas types and the 9 most important gas standards are available for measurements medical technicians and ventilator manufacturers commonly use. Settings on the CITREX H3 can be changed easily via a simple to use configuration tool. By connecting the device to a computer, operators can customize the 1.7” screen to display just the values and units they need for their measurements. The device is available as a single unit and can be expanded with various accessories and options. For the measurement of oxygen, an optional O_2 sensor can be purchased, which increases the range of application of the CITREX H3. In addition, imtmedical offers a variety of adapters, test lungs and a carrying bag — just the accessories that users need in their professional lives. As usual for imtmedical products, the features of the CITREX H3 gas flow and pressure analyser will be improved throughout its entire lifecycle. This latest measuring device already has CE and CSA certification.

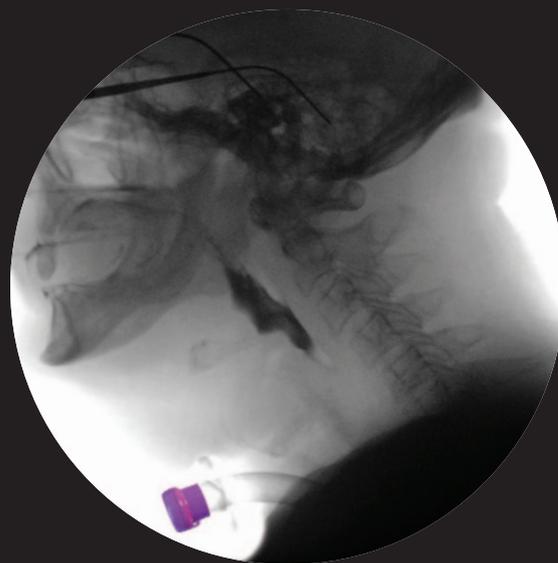
Devices Design to Hold in Place

Dale Medical Products, Inc., the company known for its high-quality, patient-friendly medical device securement solutions, is again advancing the field with its new Hold-n-Place General Purpose Securement Products. With three sizes, 950 Small, 951 Medium and 952 Large, the devices are sized to fit a wide variety of applications. They secure lines and tubes in place on the patient’s body using the familiar “hook and loop” technique with a high-quality adhesive to enhance patient comfort. Hold-n-Place General Purpose Securement devices are made with skin-friendly materials, are breathable and are made without natural rubber latex to reduce the risk of allergic reactions and skin irritation. “Keeping lines and tubes safe and secure is vital to both clinicians and patients,” says John Brezack, President of Dale. “Hold-n-Place Securement devices do so reliably while keeping patient comfort a top priority.” These general purpose devices feature a soft, comfortable, flexible design with no hard

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plastic parts. No skin prep is required for application, and no alcohol is required for removal. By securing the lines and tubes from the top, bottom and sides, the devices provide superior securement for both vertical and horizontal accidental line pulls. For more information about Dale's new Hold-n-Place Catheter Securement line, or to request a product sample, please call 800-343-3980.

Firm Adds to Mask Portfolio

ResMed introduced its first minimal-contact full face CPAP mask, AirFit F30, the latest addition to its AirFit mask portfolio, which helps users reduce facial marks, wear glasses in bed and curl up closer to their bed partner. Unlike most traditional full face mask cushions, AirFit F30's sits below the nasal bridge, preventing top-of-the-nose red marks and irritation, and reducing feelings of claustrophobia for some full face wearers. AirFit F30 also features ResMed's latest QuietAir vent, so it's quieter than ambient noise in the bedroom. Plus, magnetic clips make the mask fast and easy to put on and take off, while a one-size-fits-all headgear ensures an accurate, first-time fit. Compared to the leading minimal-contact tube-down full face mask, 80% of users said AirFit F30 was easier to use; 66% of users said AirFit F30 had a more stable fit and better seal, and users found it quieter, based on published performance (21 vs. 32.5 dBA). With just two cushion sizes and one headgear, AirFit F30 fit 93 percent of users in a ResMed study. Fast and accurate first-time fittings with fewer stock keeping units (SKUs) can help home medical equipment (HME) providers achieve higher patient satisfaction, successful patient setups and simpler inventory management. "AirFit F30 is a win-win for sleep apnea patients and HMEs, and the perfect addition to ResMed's portfolio of CPAP masks," said Jim Hollingshead, president of ResMed's Sleep business. "It provides an easier, quieter and more stable fit for full face wearers, while HMEs can enjoy faster setups and easier inventory management with a mask designed to fit the first time, every time." AirFit F30 will be available later this year in select countries. It will be on display this weekend at the European Respiratory Society Congress in Paris at ResMed's Booth J.04. *News continued on page 81...*

AARC PREVIEW

D R Burton

Booth 329

What products will you be presenting at AARC?

D R Burton is pleased to be presenting our line of oscillating positive expiratory pressure (OPEP) devices, the standard of care for airway clearance.

Are there any new products you wish to emphasize?

New this year to the D R Burton respiratory product line is our OxyJet™, an innovative venturi adapter to provide supplemental oxygen during use of the vPEP. Also new this year is the J-Wand™, intubating stylet features a flexible introducer tip to facilitate placement of an endotracheal tube (ETT).

Discuss educational/training materials you'll be offering.

Visit the D R Burton booth to see our educational and training materials including Instructional Videos, QuickStart Guides, and Inservice Posters.

What speakers or papers will you be featuring?

Visit the D R Burton booth to receive reprints of studies published in Respiratory Therapy: *Analysis of Three Oscillating Positive Expiratory Pressure Devices During Simulated Breathing; Effect of Inspiratory Time on PEF/PIF Ratio in Three Oscillating PEP Devices in an Adult Chronic Bronchitis Model; Analysis of Tidal Volume and Expiratory Pressure during Oscillatory PEP Therapy in Healthy Subjects.*

Why should AARC participants visit your display?

Visit D R Burton to see the latest innovations in OPEP therapy.

Electromed

Booth 323

What products will you be presenting at AARC?

Electromed will present the SmartVest® SQL® Airway Clearance System at AARC congress 2018. The SmartVest system uses high frequency chest wall oscillation (HFCWO), a proven therapy prescribed for people with impaired airway clearance, that helps clear the lungs of excess mucus, reducing the risk of respiratory infections and hospitalizations. The SmartVest system consists of an inflatable garment connected to a programmable air pulse generator. During therapy, the SmartVest garment delivers a rapidly repeating pulse of air, alternately squeezing and releasing the upper body. Each squeeze simulates a "mini cough," which acts to loosen, thin and propel mucus toward major airways, where it can be more readily expectorated or suctioned away.

Are there any new products you wish to emphasize?

Electromed launched the SmartVest SQL with SmartVest Connect™ wireless technology last year, a personalized HFCWO therapy management portal for patients with impaired airway clearance. The SmartVest SQL with wireless technology features built-in cellular connectivity, offering healthcare teams and patients access to treatment information to better collaborate in making patient-centered care decisions. SmartVest Connect is available online at <https://connect.smartvest.com> using a wirelessly enabled SmartVest SQL system. SmartVest Connect enables patients to track progress of their therapy plan and includes a real-time SmartVest Score and easy-to-read goal reports that provide an in-depth look at performance. Created to encourage patient engagement, SmartVest Connect provides feedback for patients to take an active role in their HFCWO therapy, fostering improved therapy adherence. Additionally, SmartVest SQL with SmartVest Connect is simple, intuitive, and designed to automatically update following completion of a therapy session: just plug it in.

What speakers or papers will you be featuring?

In two recently published case review outcome-based studies, the clinical effectiveness of SmartVest was proven by comparing a year of exacerbation-related healthcare utilization, medication, and respective costs for non-cystic fibrosis bronchiectasis patients to a standard of care control. These outcome-based studies demonstrated a significant reduction in healthcare utilization and its associated costs when bronchiectasis patients were treated with SmartVest for one year: 57% reduction in antibiotic prescriptions, 59% decrease in hospitalizations, and 60% fewer emergency department visits. And although it was not a part of the protocol, 68% of the patient population unreservedly reported a significant improvement in their quality

How long will the oxygen last at this flowrate?



Praxair's *Grab 'n Go® Digital* portable medical oxygen system now features an easy-to-read "time remaining" display, with audible and visual alerts. These alerts are designed to activate if the cylinder pressure drops below 300 psig. With no need to estimate oxygen supply, transports can be more efficient with reduced human error.

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of life after a year of using SmartVest, representing a potentially appreciable impact on overall patient well-being. An independent outcome-based clinical study was recently presented at the World Bronchiectasis Conference in Washington, DC revealing that early use of HFCWO therapy with the SmartVest system significantly reduced severe exacerbations and hospitalizations among non-cystic fibrosis bronchiectasis patients. The study is the first to report “stabilization of key lung function parameters” as a result of HFCWO use. This suggests that early bronchiectasis treatment with HFCWO may significantly slow the otherwise normal progression of the disease.

Why should AARC participants visit your display?

Feel the SmartVest difference and learn firsthand what makes the SmartVest system a preferred choice for HFCWO therapy through a hands-on demonstration. The microfiber material, ergonomic fit, and 360° oscillation coverage provides a more comfortable fit as well as the SmartVest’s pressure relief that allows patients to breathe easier during therapy. Managing symptoms like chronic cough, shortness of breath and stopping the cycle of recurrent respiratory infections with the SmartVest system can significantly reduce healthcare utilization and associated costs.

International Biophysics Corporation

Booth 913

What products will you be presenting at AARC?

We are featuring the AffloVest, our fully mobile HFCWO airway clearance device. International Biophysics pioneered mechanical oscillation with the Afflovest for airway clearance therapy for patients with severe respiratory diseases such as bronchiectasis, cystic fibrosis and other neuromuscular diseases. The AffloVest is battery operated and uses Direct Dynamic Optimal Oscillation technology that is engineered to closely mimic hand CPT to help mobilize and clear secretions, allowing for full freedom of mobility during treatment. The AffloVest features 8 built-in oscillating modules that, for the full range of 7 sizes offered, are anatomically placed to target the front and back lobes of the lung and allow for targeted customized treatment plans using the digital controller.

Are there any new products you wish to emphasize?

Our next generation AffloVest is much lighter, quieter, more efficient and has a smaller profile battery, long life — state of the art motors, and improved patient ease of use. This new AffloVest is on average 2 pounds lighter (over 20% weight reduction) than the previous version which was already by far the lightest mobile, mechanical oscillation vest on the market. This next generation AffloVest is also sleeker, more slim fit, utilizing streamlined components and tailored styling.

Discuss educational/training materials you’ll be offering.

Conference attendees can stop by the booth to learn more about several new educational initiatives we have recently introduced. This includes accredited training for RTs and case managers, and peer to peer physician modules on the symptoms and treatment of bronchiectasis.

What speakers or papers will you be featuring?

Visitors who come see us can obtain copies of our new IRB

approved Clinical Study on the effect of HFCWO on spirometry measurements. We also have the results of 2 independent lab studies, one a comparison of noise levels of all HFCWO vests currently on the market and the other a comparison of magnetic fields of the two mechanical oscillation HFCWO vests on the market. We also have 3 independent clinician papers that show lung function score improvement and this improvement being maintained over a large time period with 2 separate groups of cystic fibrosis patients that switched to the AffloVest after using air bladder technology. We are in the process of launching several new clinical studies in the months ahead.

Why should AARC participants visit your display?

Hands on demos of the AffloVest technology are a great way to see and feel firsthand the effectiveness of this treatment. Participants will see why AffloVest is becoming the state of the art oscillation treatment method. Visitors to our booth will also have access to supporting clinical studies, lab tests and clinician papers, product information, resources for prescription and reimbursement, and information on new programs we offer for patients and clinicians.

Instrumentation Industries Inc.

Booth 909

What products will you be presenting at AARC?

We will be presenting our complete line of Inline MDI Adapters, as well as Silicone Connectors, Barbed Tubing Adapters (“Christmas Tree Connectors”), Instant Flow Valves, Pilot Tube Repair Kit, Cuff Pressure Monitors, Vacuum/Pressure Gauges, and NIF Meters to name just a few of the items we will have on display at our booth.

Are there any new products you wish to emphasize?

Our latest Inline Adapter, the RTC 26-C. This adapter joins our family of other Inline Adapters. The RTC 26-C now allows the Combivent® RespiMat® Inhaler to be administered in line through a Ventilator Circuit.

Discuss educational /training materials you’ll be offering.

We will have product information sheets as well as the actual products at our booth for participants to have a hands-on experience. They can actually try the RTC 26-C.

Why should AARC participants visit your display?

We have everything needed to make Respiratory Therapy work for you. With our selection of connectors and adapters, accessories and Ventilator products, you will be able to make any connection easily. We have many difficult to find parts that are essential to do your job.

MGC Diagnostics

Booth 729

What products will you be presenting at AARC?

MGC Diagnostics® will display recent product developments and technology advancements, including systems for pulmonary function testing and gas exchange testing. Pulmonary Function

Testing systems include: The Platinum Elite™ body plethysmograph and the Ultima Series™ cardiorespiratory

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diagnostic systems. Both have RTD™ real time diffusion technology which delivers clinically significant graphic data and immediate results. Gas Exchange Testing systems include: The Ultima CPX™ metabolic stress testing system, CCM Express® indirect calorimeter and the Ultima™ CardiO2® gas exchange analysis system with integrated 12-Lead ECG. Our latest version of cardiorespiratory diagnostic software incorporates HIPAA – HITECH Security Safeguards to protect your patient's Identifiable Health Information. We will also be showcasing the CPFS/D™ USB spirometer – a full function, portable spirometer and Resmon™ PRO FULL FOT (Forced Oscillation Technique) device.

Are there any new products you wish to emphasize?

MGC Diagnostics will be highlighting the release of Ascent cardiorespiratory diagnostic software for our pulmonary function line of products. Ascent software has been designed from the ground up, resulting in the most advanced testing software platform available. Designed to function with today's hardware and with an eye on future innovations, Ascent software guides the user through the software to ensure an effective patient outcome. The unique Insight™ quality control gauge shows if an effort has passed (or failed) ATS Guidelines in real-time. Outstanding at-a-glance graphic displays and reporting functions show just why MGC Diagnostics is a leader in cardiorespiratory diagnostics.

Discuss educational/training materials you'll be offering.

Managing the MGC Diagnostics® exhibit will be our best in class clinical, sales and support staff available to answer not only your product questions, but provide expert consultation for your clinical application and cardiorespiratory business needs.

Why should AARC participants visit your display?

MGC Diagnostics® delivers diagnostic solutions for detection, classification and management of cardiorespiratory patients worldwide. This singular focus guides our strategy and defines our commitment to customers, employees and shareholders. These attributes make us uniquely qualified to solve today's challenges and uncover solutions for tomorrow's opportunities.

Neotech

Booth 717

What products will you be presenting at AARC?

Products include the NeoBar® ET Tube Holder, Little Sucker® Suction Devices, Neotech RAM Cannula®, EZCare™ Softtouch Tracheostomy Tube Holder, and NeoGrip® Tubing and Cable Holder.

Are there new products that you wish to emphasize?

Neotech is excited to announce our extended line of NeoSucker® Curved oral and nasal suction devices. We taken two of our extremely popular Little Suckers and given them an anatomically curved shape. The Preemie (N206) and Standard (N207) are the perfect complement to the previously XL (N208) which is ideal for pediatric care. NeoSucker offers a soft, flexible tip similar to a bulb syringe. Just like our entire line of suction tips.

Why should AARC participants visit your display?

Come by our booth for your free product sample bag.

Passy Muir

Booth 121

What products will you be presenting at AARC?

Pediatric Anatomical Demonstration and Teaching Model –

Passy-Muir, Inc. has added a new addition to its line of anatomical teaching models. Tracheostomy P.A.M.® Pediatric Airway Model is designed for use by healthcare practitioners to educate students, families, patients, and clinicians about tracheostomy in the pediatric airway and the proper application of the Passy Muir® Valve. Conveniently sized, Tracheostomy P.A.M. is designed to illustrate the approximate anatomy of a toddler (ages 2-4). Consistent with the anatomy of a toddler, P.A.M.'s epiglottis and vocal folds are represented in a higher position than in adults, the vocal folds are displayed in an anterior slanted position, and P.A.M.'s soft palate and tongue are larger in relation to the total size of the oral cavity. P.A.M. is packaged with helpful educational accessories to enable clinicians to provide a wide variety of education related to tracheostomy. The kit includes three demonstration Passy Muir® Valves, a cuffed tracheostomy tube, and a syringe for cuff deflation. The kit allows for education and practice related to use of a speaking valve. A nasogastric tube is provided for the display of nasogastric placement. A customized Tracheostomy P.A.M. product package is provided for easy storage and transport of the entire P.A.M. kit. Passy Muir has prepared helpful instructional videos for use of the Tracheostomy P.A.M. Pediatric Airway Model and the clinical staff at Passy Muir is available to answer any questions regarding assembly or to provide suggestions on how to use the Tracheostomy P.A.M. Pediatric Airway Model for teaching purposes. For more information, or to purchase, visit www.passymuir.com.

Updated TRACHTOOLS™ Communication App v1.3 – Now in English and Spanish, this tracheostomy patient-friendly app enables communication at the touch of a button. Featuring an intuitive menu, user-defined voice options, prerecorded phrases, a custom phrase record option, patient videos, and easy access to resources, TRACHTOOLS™ is designed to facilitate communication, provide useful tracheostomy information, and foster patient participation. The redesigned app also allows patients and clinicians to cross language barriers with a new prerecorded phrases translation feature. The app is perfect for patients, families, and caregivers. Now available free of charge from the App Store or Google Play. *At Passy Muir, better communication means better care.*

Toby Tracheapuppet™ Therapy Hand Puppet – Passy Muir

has a new addition to its family of pediatric educational products. Featuring a pediatric tube and Passy Muir® Valve for demonstration and education, the new Toby Tracheapuppet™ plush therapy hand puppet provides therapists and caregivers with a lighthearted method to introduce children to tracheostomy and the Passy Muir Valve. Perfect for interaction with young patients, the Toby Tracheapuppet facilitates vocalization and enhances therapeutic activities. For more information, or to purchase, visit www.passymuir.com

Are there any new products you wish to emphasize?

Our complete line of Tracheostomy Education Models – Our

updated family of tracheostomy education models provide healthcare practitioners with an easy way to educate students, families, patient and clinicians about airway anatomy and tracheostomy. Packaged with helpful educational accessories to

enable clinicians to provide a wide variety of education related to tracheostomy, these kits include demonstration Passy Muir® Valves, cuffed tracheostomy tube, syringe and nasogastric tube. Conveniently sized, these models are perfect for demonstration and education, and feature new customized packaging to provide easy storage and transport.

The PMV-AD1522™ and PMV-AD22™ Adapters – Available wherever you purchase other Passy Muir products, these versatile adapters are designed to provide a secure connection between the Passy Muir Valve® and a tracheostomy tube, ventilator tubing, closed suction systems, or other adapters. Each adapter is latex free, color coded for easy identification, and provided in re-sealable, multiple unit packaging. The PMV-AD1522 is a step-down adapter designed to connect the PMV® 007 (Aqua Color™) to a T-piece type closed suction system. The flexible PMV-AD22 adapter is designed for use with the PMV® 2001 (Purple Color™). All Passy Muir products are proudly made in the USA.

Discuss education/training materials you'll be offering: Icon-based reference bibliography with citations of up-to-date research specific to tracheostomy. Colorful icons make it easy to quickly find a reference by category and application.

Passy Muir Pocket Guide. Handy pocket-sized Assessment & Placement, Accessories & Connections guide featuring useful information pertaining to patient selection, airway assessment and Passy Muir® Valve placement. Includes information regarding ventilator connections, clinical benefits, care and cleaning, and therapeutic techniques.

Journal of Aerodigestive Health. Written by clinical professionals for clinical professionals, the journal features papers and research by respiratory therapists, speech-language pathologists, and physicians on the latest clinical information for working with patients with tracheostomy and the Passy Muir® Valve. If interested in contributing an article, or to learn more about how you can be involved in the journal, please email aerodigest@passymuir.com

Passy-Muir, Inc. is committed to improving the quality of life for tracheostomized and ventilator-dependent patients. To meet this mission, we provide free education through on-line self-study webinars and onsite inservices tailored to meet the needs of your facility. These educational opportunities are free and provide CEUs for respiratory therapy, speech pathology, and nursing. Visit www.passy-muir.com/education for more information. We also offer a national seminar at a nominal cost which provides 8 CEUs, delivers state-of-the-art education from both an RRT and SLP through didactic lecture, with patient videos, hands-on instruction, specialized training in ventilator application and dysphagia management, and case studies to synthesize all the information. Visit our website for 2018 opportunities still available, and stay tuned for a 2019 seminar near you – with dates and places to be announced soon. Visit www.passymuir.com for more information.

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Visiting our display gives you an opportunity to participate in interesting hands-on activities, and gain helpful insights from our expert clinical professionals. Plus, check out our adapters, the new P.A.M.™ tracheostomy pediatric airway model, our new Toby Tracheapuppet™ Therapy hand puppet, explore the

updated TRACHTOOLS™ communication app, and learn about our exciting new seminars and educational offerings.

Precision Medical

Booth 705

What products will you be presenting at AARC?

Precision Medical will be presenting our new Air Oxygen Blender accessories newly launched in June 2018. These accessories allow clinicians to individually customize their air oxygen blenders to meet every unique situation they encounter. The 2018 AARC show in Las Vegas will be the first opportunity for practitioners to view and get hands on experience with these new products.

We are also displaying our new Oxygen Analyzer and we are featuring our new Hose Retractors. We look forward to giving clinicians new and out of the box ideas for using hose retractors outside of the OR. Ideas include helping corral ventilator hoses and blender hoses where increased lengths are needed. Precision Medical is prominently featuring the redesign of our vacuum regulator gauges. Stop by and see our new vivid colored gauge faces with their intuitive layout.

Why should AARC participants visit your display?

At this year's AARC we look to bring it full circle back to the beginning. Participants should come by to reacquaint themselves with Precision Medical, a US company that has been providing quality respiratory equipment for more than 30 years. Not just assembled in the USA, but designed and manufactured in the USA. The difference is precision.

The Benefits of Data Integration for Medical Devices

In this feature, *Respiratory Therapy* interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Leslie Copper, Director, Regional Sleep and Neurodiagnostics, Oregon Region, Providence St. Joseph Health.

Respiratory Therapy: Providence St. Joseph Health (PSJH) recently integrated medical device data directly into the hospital's electronic health records (EHRs). What data did you integrate, and why?

Leslie Copper: PSJH, including Swedish, has integrated usage data from more than 40,000 cloud-connected positive airway pressure (PAP) devices into patient EHRs for more efficient and effective remote patient monitoring. The PAP data integration project has been successful with the cooperation and support of Xealth, ResMed, Philips, and many HME companies, including Performance Home Medical and Providence Home Services. Whenever you integrate a patient's therapy device data into the EHR, you help ensure that up-to-date data will be seen and considered as part of that patient's overall care plan. Plus you save the provider valuable minutes not spent toggling between hospital and device data platforms, minutes that add up every day, week and month into significant time that doctors could otherwise spend providing more quality care to more patients.

RT: How does medical device data integration work?

LC: With Xealth — a digital health platform incubated at PSJH — sleep apnea patients can be remotely monitored. The data from the patient's PAP device is now viewable right from their health record, making it accessible by the patient's entire care team. The integration relies on the Xealth digital platform, and uses APIs from the vendors without having to do a direct interface into Epic (Providence's EHR solution) — thus avoiding the cost and burden of traditional integrating. Plus, PSJH no longer has to store the data in Epic, freeing up IT team resources. Xealth also allows physicians to prescribe educational content, apps and programs for disease management.

RT: Why is it important to track sleep therapy data in the first place?

LC: Untreated sleep apnea can increase the risk of heart disease, high blood pressure, diminished blood glucose control in those with type 2 diabetes, and other life-threatening conditions. The "gold standard" treatment for sleep apnea is a positive airway pressure (PAP) device. Today, many of these devices feature cloud connectivity for remote monitoring, which is proven to improve patient adherence and clinician efficiency, and is

encouraged in the U.S. and other countries via reimbursement incentives.

RT: What is the benefit of integrating sleep data into EHRs?

LC: Advancing interoperability is key to managing sleep apnea and other chronic conditions. Without it, doctors often must access a separate monitoring platform to view a sleep apnea patient's at-home therapy data. This additional manual task takes physicians away from the patient record and prevents them from syncing up to evaluate against other conditions. With an integrated system, clinicians no longer have to "swivel chairs" between the device manufacturer's portal and the patient's EHR, saving valuable time and resources in the primary care setting. This enables the provider to spend that time delivering better patient care driven by a holistic view of patients' conditions.

RT: What factors ensure better results from patient management via connected health devices?

LC: A combination of devices with communication capabilities, providers having access to data and that data being actionable for providers, are all necessary factors to ensure better results. Only when data arrives in the right way — as information that actually improves clinical decision-making — and is accessible to the right people at the right time in the right place, will it move the practice of medicine forward.

Baseline data has already suggested that remote patient monitoring of patients with sleep apnea is a successful model to ensure compliance and optimized patient management. A study from June 2016 by Kaiser Permanente found remote monitoring and automated intervention of sleep apnea patients with ResMed's U-Sleep was shown to improve use of CPAP devices by 21 percent within a 90-day period — the standard time requirement for Medicare reimbursement — without any additional provider intervention. Useful, timely information the device sends back helps ensure proper usage and provides opportunities for remote monitoring and coaching.

Furthermore, the data will be available anytime the patient visits a different provider. In this way we hope to better manage long-term changes that affect the effectiveness of treatment.

RT: How can health systems improve the ways they collect relevant patient/medical data?

LC: One fundamental approach to capturing relevant patient/medical data is to make collection an automatic side effect of the actions that already take place. We want to innovate in ways

Leslie Copper, Director of Regional Sleep and Neurodiagnostics at Providence St. Joseph Health, about integrating PAP data into patients' EHR. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.



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that allow for secure automatic data transfer, giving the patient a chance to focus on the therapy without concern of an additional thing to manage. Device makers are enabling this by building connectivity into their devices so they can automatically transmit data back to the cloud and then straight on to the provider's desk and patient's portal.

RT: What were some challenges to this integration?

LC: EHRs aren't inherently designed to house patient-generated clinical data like sleep therapy data. As a result, there's a reasonable amount of work between the technical and clinical teams to ensure that data can securely be presented in an insightful and meaningful way. Additionally, there is a significant cultural shift required to change how all the parties involved share data. Whether PAP vendors, DME companies, or sleep specialists, all stakeholders in patient care have to let go of age-old patterns of controlling "their" data. We have to work together to put the patient at the center by seeing things from the patient perspective. With this project we've accomplished this and proven that all parties can exchange information and centrally house the sleep data for the benefit of the patient.

RT: How can Providence St. Joseph translate these digital health tools into other areas of patient care?

LC: Providence St. Joseph's commitment to look at this sleep apnea data in the context of the patient's other medical records is a promising step to even greater results and outcomes. Through the simplified access to data, providers and the care team have better and more frequent conversations with their patients about their therapy usage. Also, it provides another opportunity for patients to talk with their care team, strengthening the provider-patient relationship and leading to improved, more personalized care with timely intervention if needed. The realization of data and insights being delivered to the right person at the right time is an exciting opportunity to improve the lives of millions around the world.

RT: How can health systems like Providence St. Joseph work to harness powers of similar partnerships?

LC: Systems and vendors should avoid "walled gardens" for the data their records and devices create. Siloed data that can't make it into hospitals' or specialists' EHR systems are not useful. The power of data lies in the connections that can be made from it — we're looking at connecting the entire health ecosystem, not just creating more data that gets stuck in one place. In order to make these connections and have free-flowing data between stakeholders, the data need to be agnostic.

RT: How is this collaboration indicative of where the healthcare industry is heading overall?

LC: The future of the healthcare system involves data that provides a whole view of a patient, regardless of where the information originates. Success in improving outcomes will be grounded in the data getting to the right provider in the right moment on the right platform such that they can determine meaningful, informed care plans. Remote monitoring and digital health can be applied to essentially every discipline within medicine to create efficiency and positive change.

Effect of High Frequency Chest Wall Oscillation Vests on Spirometry Measurements

Thomas William O'Brien, MD¹, Jose Antonio Urdaneta-Jaimes, MD, FCCP, FAASM¹, James Lucio, MD, FCCP, FAASM², Susan Anne Metcalf, ARNP¹, Cathy Marie Goodwin, MA, CCRC^{1,3}

Abstract

Introduction. High-Frequency Chest Wall Oscillation (HFCWO) vests are the standard of care to help manage certain respiratory conditions. We performed this study to investigate the effects of the short-term application of motor and compressor-based HFCWO vests on the spirometry parameters and to assess if there were significant differences between the two device types.

Methods and Analysis. We conducted a prospective, three-arm study in healthy subjects for changes in TV, PEF, FVC, FEV1, and FEF25-75%. In each arm of the study, a motor-based vest (AffloVest[®] manufactured by International Biophysics Corp., Austin, TX n=10) and one compressor-based vest (The Vest[®] manufactured by Hill-Rom, St. Paul, MN, SmartVest[®] manufactured by Electromed, New Prague, MN and inCourage[®] manufactured by Respiritech, St. Paul, MN each n=10, total n=30) were evaluated. Consecutive subjects in each arm were fitted with the two different types of HFCWO vests in alternating order. Tests were performed at baseline and while using each device.

Results. There were no statistically significant differences in TV and PEF between baseline and while wearing HFCWO vests. FVC (4.12 L vs 4.29 L, p=0.019), FEV1 (3.30 L vs 3.51 L, p<0.005) and FEF25-75% (3.19 L/s vs 3.71 L/s, p<0.005) were significantly decreased in the aggregate compressor group. In the AffloVest group, FEF25-75% was significantly decreased (3.54 L/s vs 3.71 L/s, p = 0.031). FEV1 and FEF25-75% were significantly lower in the compressor-based group than in the AffloVest group.

Discussion. We show for the first time that during use compressor-based HFCWO vests significantly decreased FEV1, FEF25-75%, and FVC, while only FEF25-75% was significantly decreased in the AffloVest group. The mode of action of increased cephalad airflow bias in the lungs does not appear to be supported by the standard clinical lung function spirometry parameters measured. None of the vest groups showed statistically significant increased airflow in the lungs. This does not support increased cephalad airflow bias in the lungs during use as a mode of action for HFCWO.

1 Pulmonary Diseases Specialists, PA d/b/a, PDS Research, Clinical Research, Kissimmee, FL, USA 34741, USA; 2 Pulmonary Disease Specialists, PA, Kissimmee, FL, USA 34741, FL, USA; 3 Corresponding Author: Cathy M. Goodwin, Pulmonary Disease Specialists, PA d/b/a PDS Research, Clinical Research, 1121 N. Central Avenue, Suite A, Kissimmee, FL, USA 34741, 407-624-4831, cgoodwin@pds-cfsc.com. Trial registration number: NCT03103880.

Introduction

High-Frequency Chest Wall Oscillation (HFCWO) vests are the current standard of care to help manage certain respiratory conditions and reduce the discomfort of symptoms. HFCWO devices have long been used to treat a wide array of lung diseases, including conditions such as cystic fibrosis, non-cystic fibrosis bronchiectasis, and Chronic Obstructive Pulmonary Disease (COPD), showing significant improvement in pulmonary function during the period in which individuals wore the devices.^{1,2,3} There are currently several commercially available HFCWO vests utilizing two different technologies — one technology utilizes a pneumatic compressor connected to an inflatable garment and the other utilizes mechanical oscillators integrated into a wearable garment. However, to date there is limited clinical evidence to demonstrate the mode of action for these devices. One proposed mode of action is cephalad airflow bias⁴ however; this mechanism is not well elucidated based on existing clinical measurement methods. The methods used to measure cephalad airflow bias are indirect measurements of airflow which are taken at the subject's mouth and have not been correlated to any effects in the lungs. There is also a lack of clinical evidence in the literature via controlled human studies to support this mechanism.

Another proposed mode of action is that the physical vibration of the chest wall helps to loosen secretions via a physical vibratory/oscillatory action, similar to the action of manual Chest Physiotherapy Treatment (CPT).⁵

We performed this study to investigate the effects of the short-term application of mechanical oscillator and compressor-based HFCWO vests on the spirometry parameters Tidal Volume (TV), Peak Expiratory Flow (PEF), Forced Vital Capacity (FVC), Forced Expiratory Volume (FEV1) and Forced Expiratory Flow (FEF25%-75%). Another aim of the study was to determine if there were any significant differences in these parameters between the two device types.

Methods and Analysis Study Design

This was a prospective, single-center three-arm study in healthy subjects completed under Institutional Review Board approval. Each enrolled subject served as their own control with baseline spirometry measurements performed at three intervals; initial, middle and final. Any subject that withdrew prior to the completion of the study was omitted from the final analysis;

said subjects were replaced with another subject to ensure a full sample size was obtained.

Participants

All healthy individuals between the ages 18 and 50 were eligible for study enrollment. Subjects were screened by the investigator according to the protocol to ensure that they met the inclusion criteria. Table 1 summarizes the participants' demographics.

Table 1. Demographics Summary

Parameter	Results
Gender	13 Female (41%) / 19 Male (59%)
Age (years)	Mean: 31.7 (range 19 – 50)
Height (inches)	Mean: 67.0 (range 59 – 76)
Weight (pounds)	Mean: 180.1 (range 92 – 322)

Procedure

The study was constructed into three arms — in each arm, consisting of 10 subjects, both the mechanical oscillator-based vest, as well as one of the three compressor-based vests were evaluated. Each of the three compressor vests was tested by 10 of the 30 total subjects, and each one of the 30 was also tested with the mechanical oscillator-based device. The order of device testing alternated between the mechanical oscillator-based and the respective compressor-based vest within each group of subjects. The HFCWO vests used were the AffloVest® mechanical oscillator-based device (manufactured by International Biophysics, Austin, TX), and three compressor-based devices: The Vest® (manufactured by Hill-Rom, St. Paul, MN), SmartVest® (manufactured by Electromed, New Prague, MN) and inCourage® (manufactured by Respirotech, St. Paul, MN).

After enrollment, each subject was fitted with both an AffloVest product and a compressor-based type vest. An initial spirometry baseline was taken using standard spirometry equipment (MIR Spirolab®) and using standard spirometry procedures, according to American Thoracic Society (ATS) guidelines⁶ for TV, PEF, FVC, FEV1 and FEF25-75% without any device on the subject.

Subjects were assigned a HFCWO vest order depending on enrollment number, with the type of HFCWO vest in alternating order between subjects. An initial spirometry baseline was taken using the standard spirometry equipment and procedures, without any HFCWO vest on the subject. The first HFCWO vest was then placed onto the subject. The HFCWO vest was turned on to the maximum frequency and intensity settings, and the subject was given five (5) minutes to acclimate before the spirometry measurements were repeated while the HFCWO vest remained on. The HFCWO vest was then turned off and removed, and the subject was given fifteen (15) minutes for recovery. An interim spirometry baseline was taken using the standard spirometry equipment and procedures, without any HFCWO vest on the subject. The second HFCWO vest was then placed onto the subject. The HFCWO vest was turned on to the maximum frequency and intensity settings, and the subject was given five (5) minutes to acclimate before the spirometry measurements were repeated while the HFCWO vest remained on. The HFCWO vest was then turned off and removed, and the subject was given fifteen (15) minutes for recovery. A final spirometry baseline was taken using the standard spirometry equipment and procedures, without any HFCWO vest on the subject.

Data Analysis

Lung function test results for the parameters TV, PEF, FVC, FEV1, and FEF25-75% were analyzed.

A Student's t-test was performed at the 95% confidence level to determine statistically significant differences between the different compressor-based devices with regard to the change from baseline for each parameter. Data from each arm of the study was compared to the two other arms corresponding to the other two compressor-based devices as well as to the aggregate data set.

A paired Student's t-test was used at the 95% confidence level to determine statistically significant differences between the baseline and during use parameter values for the mechanical oscillator-based group compared to baseline as well as for the aggregate compressor-based device group compared to baseline.

A paired Student's t-test was used at the 95% confidence level to determine statistically significant differences between the during use parameter values for the mechanical oscillator group compared to the during use parameter values for the aggregate compressor-based device group.

Results

Thirty-two subjects were enrolled and two subjects withdrew. Two additional subjects were enrolled to replace the two subjects who withdrew.

There were no statistically significant differences between any of the different compressor-based devices with regard to change from baseline for any of the tested spirometry parameters. It was concluded that data from the three compressor device arms could be pooled (the "Aggregate Compressor Device Group"). There were no statistically significant differences between any of the different mechanical oscillator-groups with regard to change from baseline for any of the tested spirometry parameters. It was concluded that data from the mechanical oscillator device could be pooled (the "Aggregate AffloVest Device Group").

There were no statistically significant differences found in TV or PEF from baseline for both the AffloVest group and compressor groups (Table 2). There was a statistically significant decline in FVC from baseline for the compressor group (4.12 L vs 4.29 L, $p=0.019$) as well as in FEV1 (3.30 L vs 3.51 L, $p<0.005$), and in FEF25-75% (3.19 L/s vs 3.71 L/s, $p<0.005$). There was a statistically significant decline found in FEF25-75% from baseline for the AffloVest group (3.54 L/s vs 3.71 L/s, $p=0.031$).

The results were further analyzed to determine whether there was any statistically significant difference between the AffloVest and compressor groups for each of the measured parameters (see columns "p-value AffloVest vs Compressor") to analyze for significant differences between the groups.

There was a statistically significant decline in FEV1 for the compressor group compared to the AffloVest group (Mean = 3.30 L, 95% confidence interval [2.96, 3.63 L] vs 3.46 L, [3.11, 3.81 L], $p<0.005$), see Figure 1. In the compressor group, there was a 6.0% decline in FEV1 compared to baseline. In the AffloVest group, there was a 1.4% decline in FEV1 compared to baseline, see Figure 1.

Table 2. Group Analyses vs Baseline

Parameter	Baseline Mean [Range]	AffloVest Mean [Range]	p-value	Compressor Mean [Range]	p-value	p-value AffloVest vs Compressor
*TV (L)	0.93 [0.30 – 2.32]	1.00 [0.27 – 2.28]	n.s.	1.07 [0.24 – 2.69]	n.s.	n.s.
*PEF (L/s)	8.19 [3.96 – 11.82]	8.28 [3.50 – 12.00]	n.s.	8.13 [4.23 – 12.89]	n.s.	n.s.
*FVC (L)	4.29 [2.48 – 6.57]	4.25 [2.50 – 7.42]	n.s.	4.12 [2.29 – 6.73]	0.019	n.s.
*FEV1 (L)	3.51 [2.05 – 5.54]	3.46 [2.00 – 6.19]	n.s.	3.30 [1.92 – 5.83]	< 0.005	< 0.005
*FEF25-75% (L/s)	3.71 [1.77 – 6.43]	3.54 [1.63 – 6.37]	0.031	3.19 [1.19 – 6.22]	< 0.005	< 0.005

*American Thoracic Society (ATS) guidelines for lung function parameters.

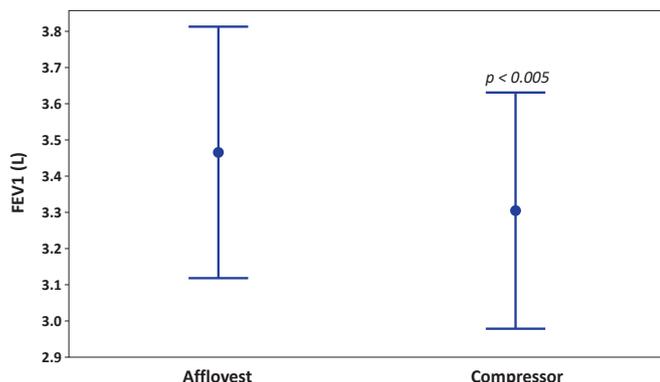


Figure 1. Figure 1 shows the comparison of FEV1 between the AffloVest group and the compressor-based HFCWO groups. The means and 95% confidence intervals are shown.

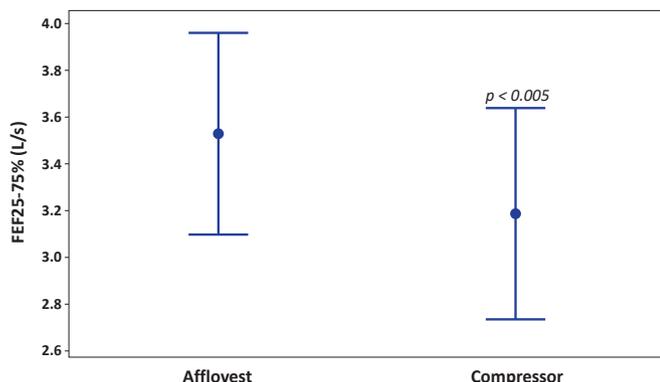


Figure 2. Figure 2 shows the comparison of FEF25-75% between the AffloVest group and the compressor-based HFCWO groups. The means and 95% confidence intervals are shown.

There was a statistically significant decline in FEF25-75% for the compressor group compared to the AffloVest group (Mean = 3.19 L/s, 95% confidence interval [2.75, 3.63 L/s] vs 3.54 L/s, [3.11, 3.96 L/s], $p < 0.005$), see Figure 2. In the compressor group, there was a 14.0% decline in FEF25-75% compared to baseline. In the AffloVest group, there was a 4.6% decline in FEF25-75% compared to baseline.

Discussion

Despite the widespread clinical use of the HFCWO devices, little has been published regarding the vests' effects while in use on standard spirometry measurements — TV, PEF, FVC, FEV1 and FEF25-75%. In this study, we report for the first time that

compressor-based HFCWO vests while in use led to a significant decrease in FVC, FEV1 and FEF25-75% during use from baseline and that a less pronounced statistically significant decrease in FEF25-75% was observed with the AffloVest. There was no effect on TV or PEF.

An earlier study with a compressor-based device in patients with cystic fibrosis found no significant effect on FEV1. However, in that study FEV1 measurements were taken before treatment with HFCWO vests and 30 minutes after treatment, with no FEV1 measurement taken during actual use of the HFCWO vest.⁷ This suggests that the impact observed in this study to the spirometry measurements (FVC, FEV1, FEF25-75%) only occur during use of the HFCWO vests.

It is not immediately apparent why FEV1 and FEF25-75% were decreased, while PEF was unaltered in our study. The mode of action of HFCWO vests is not fully understood at this time. The purpose of the device is to mobilize pulmonary secretions, which is done by creating oscillations of the chest wall. It has been reported that induced cephalad airflow bias results in increased mobilization of mucus.^{8,9} It has also been speculated that increased cephalad airflow is the mode of action of HFCWO vests. However, the link between alterations in airflow and the mobilization of mucus has never been established through clinical studies in humans using HFCWO vests. Furthermore, airflow measurements which are taken at the subject's mouth, have not been correlated to any effects in the flexible airways, where cephalad airflow bias results in mucous mobilization.¹⁰

Based on the concept of increased cephalad airflow bias in the lungs during use of HFCWO devices, one might expect that the expiratory peak flow should be increased. However, our study in healthy volunteers showed no increases in PEF in any of the HFCWO vest groups. On the contrary, we demonstrated a decrease in the expiratory airflow parameter FEF25-75%, suggesting that the concept of HFCWO vest-induced cephalad airflow bias is not supported by standard spirometry measurements.

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Proportional Pressure Support (PPS)

Clinicians successfully match patients' respiratory demands and facilitate weaning by using PPS – A Case Study

Brian Stewart, BA, RRT, NPS

The patient is a 72-year-old female transferred to our facility with acute respiratory failure, hypoxia, lactic acidosis, septic shock, and acute renal failure. Her history includes significant COPD, CVA, diabetes mellitus type 2, tardive dyskinesia, hyperlipidemia, hypothyroidism, and depression. After being sedated with Propofol and Fentanyl, she was started on Levophed and IV fluids. Her respiratory rate was 33 with obvious accessory muscle use. Her arterial blood gas showed a severe metabolic acidemia.

Initial Arterial Blood Gas Results

pH	7.01
PaCO ₂	15
PaO ₂	182
HCO ₃	3.7
BE	-25.7

Initial Ventilator Settings

Application Mode	VC/AC with AutoFlow
Tidal volume (Vt)	400 ml (8 ml/kg of ideal body weight)
Respiratory Rate	14, PEEP 8
FiO ₂	1.0

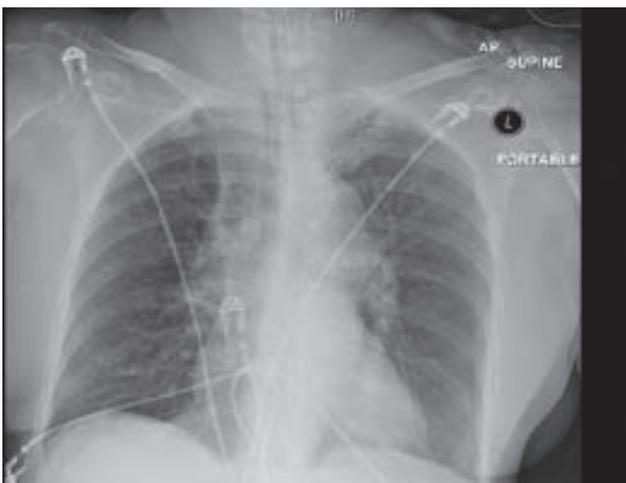


Figure 1. Initial chest X-ray

Brian Stewart has been a Respiratory Therapist since 1991. He is currently the Adult Critical Care Coordinator at Carle Foundation Hospital in Urbana, IL. His passion is to research potential therapies and seeing positive outcomes after bringing them into everyday practice.

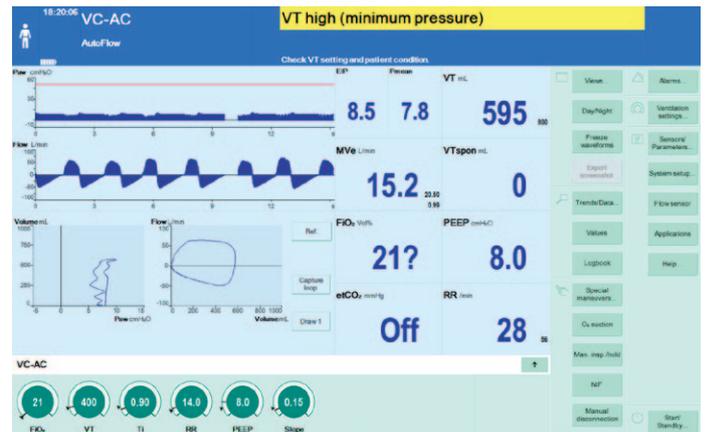


Figure 2. Initial ventilator settings

The initial mode of ventilation was VC/AC with AutoFlow. Given the erratic spontaneous breathing despite moderate sedation, this approach needed to be altered for the condition at hand. To help correct her acidemia, the patient was taking larger than set tidal volumes (Vt). The patient's respiratory drive needed to control the level of support provided by the ventilator.

The mode of ventilation was changed to Proportional Pressure Support (PPS). The thought was to allow the patient to take control of ventilation. As the acidemia resolves, her respiratory drive should decrease, as would Vt and spontaneous rate.

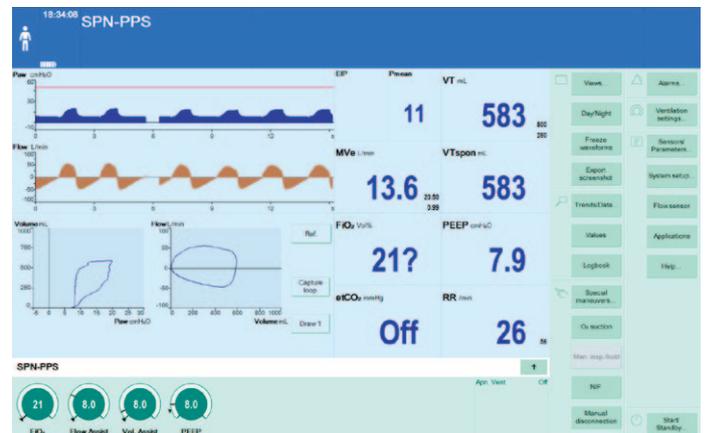


Figure 3. Initial PPS settings

The patient was able to take the Vt she desired. Her accessory muscle use diminished and she appeared much more comfortable. Initial PPS settings were 8 of flow assist and 8 of

volume assist. Over a period of time, the flow assist control was adjusted to 4 and the volume assist was adjusted to 13.5. Automatic Tube Compensation was also added to overcome the patient's resistance to the endotracheal tube.

in proportion to her effort allowed for effective management. Through the use of PPS, the clinicians were able to match the patient's respiratory demands and facilitate weaning from the ventilator.



Figure 4. Addition of Automatic Tube Compensation

As the patient's acidemia resolved, the PPS settings were manipulated based on work of breathing, airway resistance, and compliance. Flow assist was set to 5.5 and Volume assist was adjusted to 12.0 by the next morning. The patient's peak inspiratory pressure, (PIP) had dropped from 30 to 12. Spontaneous tidal volumes were much more variable, and her spontaneous respiratory rate improved to the low 20/min.



Figure 5. Variable Tidal Volumes (Day 2)

ABG Results Show An Improved Acid Base Balance

pH	7.38
PCO ₂	25
PO ₂	114
HCO ₃	14.1
BE	-9.6

The patient was kept on PPS mode until she was alert. The clinical team believed that the patient could be extubated at this time. At this point the patient was placed on CPAP with pressure support for a brief spontaneous breathing trial and extubated.

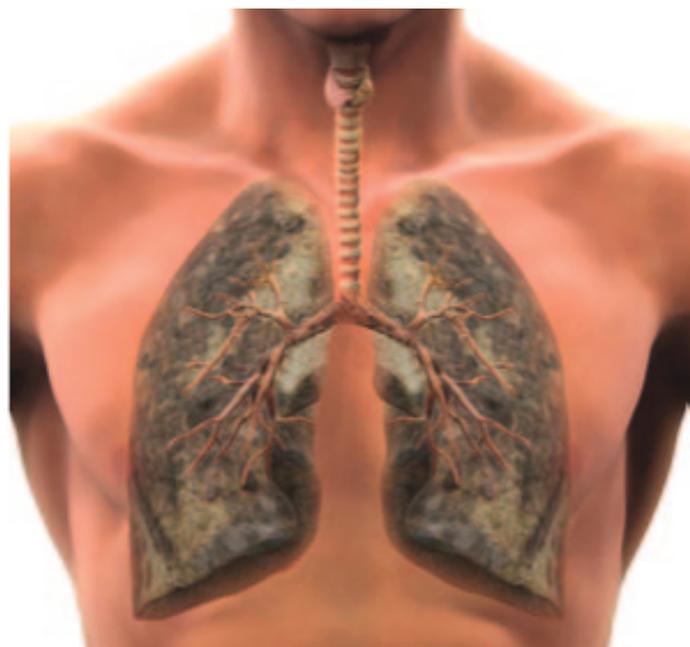
Conclusion

Proportional Pressure Support (PPS) can be a useful mode when the patient requires breath by breath adaption to support their own inspiratory demands, while unloading work of breathing. In this case, supporting the patient's spontaneous breathing

Shining a Spotlight on the Dangers of Respirable Crystalline Silica

Occupational Dangers to Lung Health

The impact on lung health of respirable silica dust (RSC) and asbestos and the risks faced by construction workers exposed to potentially harmful substances are key areas of focus for UK HSE and local authority inspectors during 2017. In a similar manner, the US government recently issued rulings to better protect workers exposed to respirable crystalline silica. OSHA has issued two new respirable crystalline silica standards: one for construction, and the other for general industry and maritime. OSHA will begin enforcing most provisions of the standard for construction on September 23, 2017, and for general industry and maritime on June 23, 2018.



As a world-leading manufacturer of respiratory devices with a heritage of supporting early detection of lung disease for over half a century Vitalograph welcomes these initiatives.

The danger of asbestos exposure causing illnesses such as mesothelioma and lung cancer are well documented however the public knows little of the dangers of exposure to RSC which may be equally dangerous. Is it possible that some cases of lung disease attributed to asbestos are actually caused by respirable silica?

Article submitted by Vitalograph Inc., Lenexa, KS, USA.

With only minimal exposure to asbestos is enough to cause harm it takes high levels of exposure to RSC to cause of conditions such as silicosis, lung cancer, TB and chronic obstructive pulmonary disease (COPD). These high levels of exposure are regrettably common as respirable crystalline silica is too fine to see and is often not considered harmful.

Those at most risk are people who have worked in foundry, cement or quarry works, stone masons, building materials manufacturers, sand blasters and those who work in the construction of roads and buildings. Millions have been paid in personal injury compensation claims for asbestos exposure illnesses. Compensation for illnesses caused by crystalline silica exposure is likely to follow soon.

What is Silica Dust?

Silica is commonly found in nature as sand. Silica exists in many different forms that can be crystalline as well as noncrystalline (amorphous). Quartz is the most common form of crystalline silica and is the second most common mineral on the earth's surface. It is found in almost every type of rock i.e. igneous, metamorphic and sedimentary and is a basic component of soil. RCS dust may be fine enough to inhale deep into the bronchioles and alveoli causing serious harm.

Crystalline silica content of different materials	
70-90%	Sand & Sandstone
25-70%	Concrete & Mortar
30-45%	Tiles
20-45%	Granite
20-40%	Quarried Slate
0-30%	Bricks
0-2%	Limestone & Marble

Protective Measures

New measures to protect workers from the dangers of silica dust are being introduced on both sides of the Atlantic. From June 23, all US firms involved in construction, maritime and general industries must follow new controls aimed at preventing hundreds of deaths and around 900 new cases of silicosis each year.

Key measures in the new standard issued by the Occupational Safety and Health Administration (OSHA) include a requirement

for employers to monitor the health of workers who are exposed to high levels of respirable crystalline silica (RCS). Additionally, highly-exposed US workers must be given feedback about their lung health.



This month also sees the six-month anniversary of a British cross-industry campaign to raise awareness of the hazard posed by RCS, which is believed to cause 800 lung cancer deaths in the country each year. Led by the Institution of Occupational Safety and Health (IOSH), the No Time To Lose campaign is due for a progress review in November.

New rules to protect US coal miners from coal workers' pneumoconiosis (CWP), a silicosis-like disease also known as 'black lung', are also due to be introduced next year. From February 2018 the use of approved facilities and spirometry devices are mandatory for all medical facilities involved in the Coal Workers' Health Surveillance Program (CWHSP). Ongoing global initiatives that highlight the danger to lung health associated with workplace exposure to hazardous substances are vital in preventing thousands of needless deaths and protecting the quality of life of employees across a wide range of industries.

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- IOSH Silica agreement six months on. www.iosh.co.uk/News/OSHA3096/3096.html
- Silica-agreement-6-months-on.aspx Spirometry Manufacturer & Model Information for Clinics. <https://www.cdc.gov/niosh/topics/cwhsp/ManufModelInfoClinics.html>
- United States Department of Labor, Occupational Safety and Health Administration on Silica: <https://www.osha.gov/dsg/topics/silicacrystalline/>

Approved CWHSP medical facilities interested in providing respiratory health screening for miners must use spirometers that:

- Meet compliance with American Thoracic Society (ATS) performance standards.
- Satisfy specific NIOSH requirements regarding the content of spirometry test reports.
- Produce output data in standardized electronic spirometry data file format by February 2018.

Electronic spirometry data files must include raw, Flow data points, at ≥ 100 Hz, for each forced expiratory maneuver. This allows NIOSH to reconstruct individual maneuver spirometry curves for quality review of coal miner spirometry test reports. The table below informs potential and participating CWHSP

approved spirometry facilities of spirometers that currently meet or have expressed an interest in working towards meeting all NIOSH CWHSP regulatory requirements. Prior to February 2018, CWHSP approved clinics are able to submit to NIOSH CWHSP spirometry reports in PDF format. After February 2018, NIOSH requires that spirometry clinics submit CWHSP spirometry reports via electronic data transfer in CSV or XML format.

Manufacturers currently not listed in the table and who are interested in furthering the objectives of this public health program can participate by ensuring their equipment meets NIOSH's regulatory standards and electronic data transfer capabilities. Information is available at: <https://www.cdc.gov/niosh/topics/surveillance/ords/coalminerhealth.html>. This table will be monitored and periodically updated to reflect which spirometer models either currently satisfy or are being modified to comply with NIOSH's spirometry reporting and electronic data transfer requirements.

NIOSH CWHSP Spirometry Table

Manufacturer	Model	Software Version	CWHSP PDF report printout approved	Manufacturer developing electronic data transfer for this model	Electronic data transfer file approved
Benson	CCS-200 / Plus	Version 8.10	X	X	X
COSMED	Microquark	OMNIA	X	X	
	Quark	OMNIA	X	X	
	Pony FX	OMNIA	X	X	
Depisteo	SPIROLYSER	Q13 SpirowinExpert		X	
Morgan Scientific	Pneumotrac	ComPas	X	X	
	Body	Plethysmograph	X	X	
ndd Medical Technologies, Inc.	Easy on-PC		X	X	X
	EasyOne Air		X	X	X
	EasyOne Pro/LAB		X	X	X
nSpire	KoKo		X		
Vitalograph	Pneumotrac	Spirotrac Version 1.19	X	X	X
	COMPACT Workstation	Spirotrac Version 1.19		X	X
Schiller Americas	SpiroScout				
	DS-20				
Vyaire Medical (formerly CareFusion)	Vyntus Spiro	SentrySuite 2.21	X	X	X
	Masterscreen	SentrySuite 2.21	X	X	X
	Masterscreen (with JLAB)		X		
	Vmax Encore (all models)		X		

Table last updated 06/04/2018

Do Home Spirometers Require Filters?

James Martins, MSc (c), BSc, Bevin McMullin, PhD, MappSc, RRT, Chris Miller, PhD, BA, RRT

Patients performing lung function tests at home have expressed concerns as to whether they need to use pulmonary function filters on their spirometers. Considering the cost of filters, it could be a barrier to performing frequent measurements. We explored the impact of patients exhaling microorganisms into their spirometer without use of a filter and the likelihood of them re-infecting themselves with subsequent tests.

Background

For almost two centuries, spirometers were used by patients without complete circuit disinfection between patients.

Hygiene was limited to changing out the mouthpiece that went in the patient's mouth. In the early 1900's, some institutions using volumetric measuring devices such as dry rolling seal, wedge or water seal spirometers would change the hoses, valve and mouthpiece between subjects without concern for cross contamination from the air in the spirometers. It wasn't until the mid to late 1970's that institutions began using spirometer filters on their equipment to minimize the risk of cross contamination.

There have been limited reports in the literature regarding the potential for cross contamination using spirometers. While there have been a handful of studies reporting on the bacterial load in spirometers, there is only one *in-vivo* study evaluating the mobilization of microorganisms between patients. Burgos, et al, studied the contamination of spirometers in fifty-four patients and then the actual effect on subsequent patients.¹ They disinfected their spirometers before starting the trial and then sampled after each patient. Ninety percent (90%) culture samples from the water-sealed spirometer showed microbial growth with prevalence of *Penicillium* sp. (62%), *Pseudomonas fluorescens* (32%), and *Burkholderia cepacea* (48%). While they were able to demonstrate contamination of the spirometer, they found that they could not demonstrate any transmission sequence of potentially pathogenic microorganisms from the equipment to patients or vice versa.

One of the only studies suggesting microbe mobilization from spirometers was by Bracci, et al.² Using a mechanical syringe system they pulled air back into the syringe through a microbial collection filter from an unfiltered spirometer.

These spirometers were used on a patient immediately before a test on a subsequent patient and they identified the potential for microbe mobilization between patients. Their conclusion was that this droplet contamination was more likely when spirometers were used immediately between subjects. They also found that turbine spirometers mobilized more organisms than Fleisch type flow meters attributing it to the spinning vane. However, they hypothesized that "use of a heated pneumotachograph, or drying the spirometers between subjects, would probably have reduced the risk of bacterial mobilization related to the presence of condensation and droplets of sputum". Zhang, also suggested flushing air through the sensor by a calibration syringe or an unheated hairdryer after each subject to remove condensation to reduce the likelihood of cross contamination.³

Heibert, et al.⁴ studied the retrieval of nonpathogenic *Escherichia coli* after aerosolizing organisms into standard pulmonary function tubing for volume spirometers. The arrival of the aerosol at the distal end of the tubing was documented by culture. After delays of 0, 1, 5, and 10 min, respectively, air was forcibly withdrawn from the proximal end of the tubing through a special petri plate assembly. The plates were cultured and the colonies were counted. Immediately after insufflation of organisms, air withdrawn from the proximal tubing had counts similar to the air sampled at the distal end. After a 1-min delay, the proximal samples contained only rare organisms. No organisms were recovered from proximal air samples after a delay of 5 or 10 min after insufflation of organisms. They concluded that "the absence of detectable aerosolized *E. coli* after delays of 5 and 10 min after insufflation of organisms into spirometry tubing supports the hypothesis that a significant transfer of aerosolized organisms does not occur during routine pulmonary function testing as long as an interval of 5 min or more is allowed between tests."

Kendrick, et al.,⁵ reported on a practical approach to infection control in lung function and included a review much of what has been reported in the literature. While concluding that there is no data to indicate cross contamination between patient from lung function equipment, they noted that there is no data on unheated spirometers, turbine spirometers or hot-wire spirometers.

Pulmonary function filters are single use items costing between \$0.35 and \$2.00 each. For patients self-testing at home on a daily basis, this cost could make the test financially prohibitive.

The authors are with the Faculty of Medicine, Respiratory Division, University of British Columbia, Vancouver, British Columbia, V6H 3Z6, Canada.

Because these patients usually test themselves once a day, it was determined that we should test the effects of heavy contamination of a turbine spirometer that was allowed to rest overnight and then tested the following day for microbe mobilization.

Purpose

To test whether a single-patient use spirometer would likely re-inoculate a patient with their own bacteria when reused without a filter.

Procedure

Each test series was done in two stages, a turbine contamination stage followed by 24 hours in a warm room temperature incubator and then followed by a stage where the mobilization of bacteria was evaluated. These were performed with both aerosolization contamination and direct swab placement of bacteria.

Aerosolized Contamination

Stage 1

Pseudomonas aeruginosa was grown in BHI broth overnight. Bacteria was diluted in saline to achieve a 10^5 cfu/mL concentration. Three (3) mL of the microbial solution was added into a standard small volume nebulizer which was attached to the mouthport side of the turbine from a GoSpiro® (Monitored Therapeutics, Inc, Dublin, OH) spirometer. Using 6 L/min air flow, the solution was aerosolized for about 30 seconds. A Blood-Heart-Infusion (BHI) agar plate was placed approximately 1 cm below the exit port of the spirometer turbine to catch aerosolized bacteria to confirm the delivery of the *P. aeruginosa*. A swab was also taken from the inside of the spirometer turbine outlet and plated.

The plates were placed into a 37°C incubator while the spirometers were placed into sterile containers and in a 30°C incubator overnight to simulate a warm environment that might be more amenable to bacterial reproduction and growth. This procedure was repeated for three (3) turbines.



Figure 1: Turbine contamination setup with aerosolized bacterial suspension passing through spirometer.

Stage 2

The following day, each spirometer turbine was connected at its outlet to a 3 L syringe from the bottom side (Figure 2). Three litres of air were pumped at >300 L/min to simulate inhalation back through the device. On the mouth side a BHI plate was placed about 1 cm below the mouthport of the spirometer turbine in a similar position and distance to contamination stage to capture any aerosolized bacterial particulates. This was performed for the three turbines.



Figure 2: Inspiratory test setup of 3 L syringe attached to the bottom side of the spirometer with a mass flow meter in line. Filter was placed at the inlet of the turbine to ensure that air was “clean” prior to entry into the contaminated end of the spirometer.

Results

Confirmation of contamination was demonstrated by confirming bacterial growth after aerosolizing the bacterial suspension and through the growth that was found from samples obtained during the aerosolizing process (Figure 3a). However, no bacterial growth was found from samples obtained from swabbing or forcibly blowing air through the opposite end (Figure 3b).

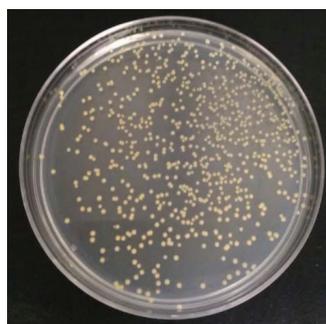


Figure 3a: Positive Control: Bacterial growth obtained during the aerosolizing process. BHI plate was placed under the bottom of the spirometer to catch aerosolized particles.

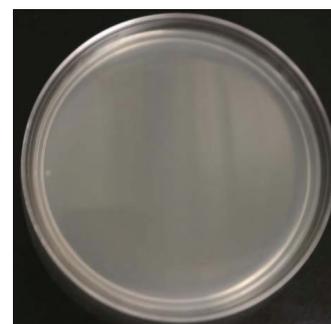


Figure 3b: Following day test plate: BHI plate was placed under the mouthport of the spirometer to catch aerosolized particles showing no growth.

Direct Bacterial Contamination

Stage 1

The following procedure was done to represent a full positive contamination with a large bacterial surface contamination within the spirometer. *P. aeruginosa* was grown in BHI broth overnight. Bacteria ($\sim 10^8$ cfu/mL) was swabbed directly onto the spirometer turbine at both the elbow that is located very proximal to the patient interface and on the internal blades at the distal area of the spirometer. From a smaller area than the inoculation, a swab surface sample was taken as a positive control and plated onto BHI plates to confirm contamination.

The plates were placed into a 37°C incubator while the spirometer turbines were placed into sterile containers and in a 30°C incubator overnight to simulate a warm environment that might be more amenable to bacterial reproduction and growth. This procedure was repeated for three (3) turbines.

Stage 2

The following day, each spirometer turbine was connected at its outlet to a 3 L syringe from the bottom side (Figure 2). Three litres of air were pumped at >300 L/min to simulate inhalation back through the device. On the mouth side a BHI plate was placed about 1 cm below the mouthport of the spirometer turbine in a similar position and distance to contamination

stage to capture any aerosolized bacterial particulates. This was performed for the three turbines.

Results

No bacterial growth was found from samples obtained by forcibly blowing air back through the device towards the proximal end where the patient would be inhaling through their mouth (Figure 4b). To confirm the continued presence of bacterial growth within the device, a swab sample was taken from the inner surface of the elbow of the spirometer turbine and incubated for another 24 hours. This sample showed bacterial growth on the BHI plate (Figure 4c).



Figure 4a: Swab after inoculation: Bacterial growth obtained by swabbing after inoculation of spirometer.

Figure 4b: Following day test plate: BHI plate was placed under the mouthport of the spirometer to catch aerosolized particles showing no growth.

Figure 4c: Following day swab: Bacterial growth obtained by swabbing the spirometer after the following day.

Conclusion

Based on these data, and assuming patients wash the mouthport adapter from the spirometer and allow their turbine to dry overnight, it is unlikely that a subject will re-inoculate themselves by re-using the spirometer without a filter. We conclude that there is a very low to no chance that bacteria will be aerosolized and then subsequently inhaled and that it is safe for single patients to use their home spirometer without a filter. We do note that for some spirometers, there might be a concern with large exhaled particle altering the characteristics of the flow sensor such as in Fleisch type pneumotachs and causing these sensors to produce erroneous results. Each spirometer should be evaluated individually to determine if this is a concern.

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Multidisciplinary Approach for the Post-Operative Cardio-Thoracic Open-Heart Patient

Michael Richardson BBA, RRT-NPS, Amy Reiner MSN, RN, Susan Miller BS-RRT, Kelly Cresci MS, RRT-NPS

Abstract

Purpose: The goal of creating an atmosphere that embodies a multidisciplinary approach that permits the best patient outcomes.

History: Prior to 2014 60% of the open hearts were thought of as being fast trackable. The CVTS team believed that 80% should be fast trackable and 20% would not be due to post-operative complications. In 2015, a new fast track open heart protocol was initiated to set and overcome a goal and bring several patient care specialties together. The group of specialties work together to help develop a team aspect and hold one another accountable to extubate our open hearts patients within a 6-hour window post-operatively. The specialties involved are the Cardio-thoracic surgeons (CVTS), Cardio-thoracic physician assistants (PA-C), the bedside registered nurse (RN) and the respiratory therapist (RRT).

Each year, from the period of 2014-2017, we have improved our team communication, patient satisfaction, and created an environment streamlined for the patients for whom we provide care. From the time a patient arrives at their critical care room post-operatively, close loop communication is made between the team from start to finish.

Method Needed

Creating a multidisciplinary team to improve patient outcomes takes patience and perseverance. Each team needs to know their piece to the puzzle and each team needs to work to setup the next team for success. Our team starts with Cardio-thoracic surgeons and their excellent skill prolongs life and without their ability, the progression of this protocol does not begin.

The multidisciplinary team is made up of the cardio-vascular thoracic surgeons (CVTS), their physician assistants (PA-C), bedside nursing (RN), and the respiratory therapist (RRT). Each discipline has their specialty and without one of the team members our success would not have been possible.

Michael Richardson is the Respiratory Care Team Leader for Cardio-Thoracic Surgery at Geisinger Medical Center. Amy Reiner is a Nursing Educator for Cardio-Thoracic Intensive Care Unit at Geisinger Medical Center. Susan Miller is the Respiratory Care Team Leader at Geisinger Jersey Shore Medical Center. Kelly Cresci is the Operations Director for Respiratory Care Services at Geisinger Medical Center.

Team Players

Anesthesia maintains the patient in the OR and sustains the patient through the surgical case, making it possible for the surgeons to have access to the patient. Mechanical ventilation and sedation are in place to promote a successful case. Anesthesia is committed to assisting the patient towards a rapid, safe extubation, and decreased intubation times post open-heart surgery.

Fast Track Protocol: OR Based

Within an hour of the projected end time for the case, avoid the use of long-acting sedatives (benzodiazepines) & higher dose narcotics. Prior to leaving OR, CRNA will perform respiratory recruitment maneuvers & give bronchodilators (as indicated). If hemodynamics permit, start Propofol @ 10-50 mcg/kg near the end of the case & maintain to CVT- ICU.

Our anesthesiologists have worked with our critical care team in the following ways: 1. Careful dosing of benzodiazepines and narcotics particularly late in the case. 2. Careful dosing of muscle relaxants with the intention of the patient arriving to the unit post-procedure with several twitches reflective of being in a 'reversible' state giving reversal agents at bedside. Anesthesia reports clinically appropriate education to all interested staff regarding muscle relaxants, mechanism of action, and reversal.

Communication is made between the respiratory therapist staff and anesthesia regarding any issues that may have occurred in the operating room from ventilation and oxygenation issues to difficult intubation. This communication is key and allows for bedside team collaboration to farther extend. If the patient is noted to have significant atelectasis or oxygenation issues post-surgery, the bedside respiratory therapist has the option of performing a PEEP maneuver of + 25-30, for 30 seconds to reverse the **patient's** post-operative atelectasis which improves patient acid/ base status and oxygenation. Again, this is an effort to aid the team in getting our patients extubated within the 6-hour window.

The bedside RN admits the patient, aids in the hemodynamically stability of the patient, and communicates regularly with the PA-C and the bedside RRT. Together, they look to maintain acid/base status of the patient along with their post-operative oxygenation.

Fast track protocol: Unit Based CRNA to RN

Following sign-out between CRNA and RN, the CRNA will assess the current neuromuscular blockade. If patient shows evidence

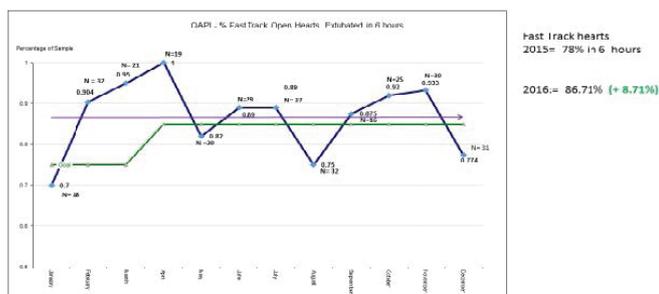


Figure 1. The goal was set at 85% in 6 hours. 8 out of 12 months the results were greater than 85% in 6 hours.

of recovery from neuromuscular blockade, then the CRNA will give reversal agents prior to leaving the patient's room. If the patient shows no evidence of recovery from neuromuscular blockade, the RN's goal is to give the reversal agents within 30 mins upon arrival to the cardiac intensive care unit. The RN will avoid the use of long-acting sedatives (i.e. benzodiazepines) and higher dose narcotics.

The Cardio-thoracic PA-C assist surgeons in the operating room and assist in maintaining patient stability post-operatively and give guidance to both the bedside RN and the RRT. Once the patient arrives to our intensive care unit an arterial blood gas is obtained within 5-10 minutes. This sample is not utilized to correct the mechanical ventilation portion post-operatively now. However, we can use to question the effectiveness of the manual ventilation of the patient from the OR to the unit. It is now that the RRT identifies the need for intervention via PEEP maneuver to aid in improving the patient's PAO₂ and attempt to reverse the effects of post-operative atelectasis. Primarily, results of this arterial blood sample to give quick feedback to the PA about the patient's electrolyte balance (i.e. ionized calcium, potassium, and sodium). However, if the PO₂ exceeds our oxygenation protocol then the F_IO₂ is decreases accordingly.

30 minutes post admission, another arterial blood gas is obtained for the RT to evaluate for a potential to adjust the mechanical ventilation settings to correct respiratory acidosis or alkalosis. Once the patient starts to become more alert, initial bedside communication between the RN and RRT is made. The PA-C is contacted to evaluate the patient and to give the approval for the RRT to start the patient on a ventilator liberation weaning trial and prepare for extubation.

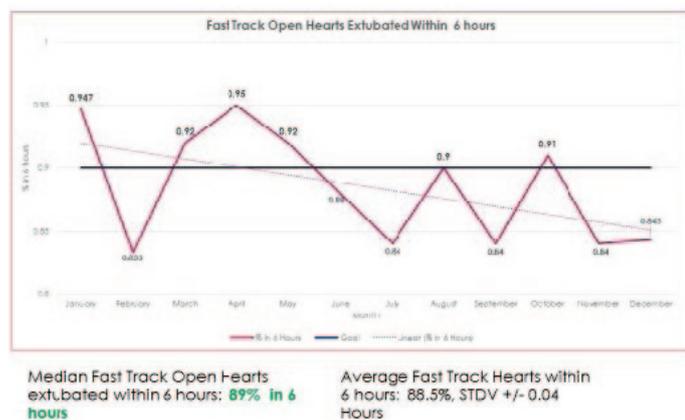


Figure 2. Looking at figure one you can see the goal set vs monthly outcome. 6 months out of 12 we were able to extubate the fast trackable open hearts ≥90% for the month. The lowest month was February.

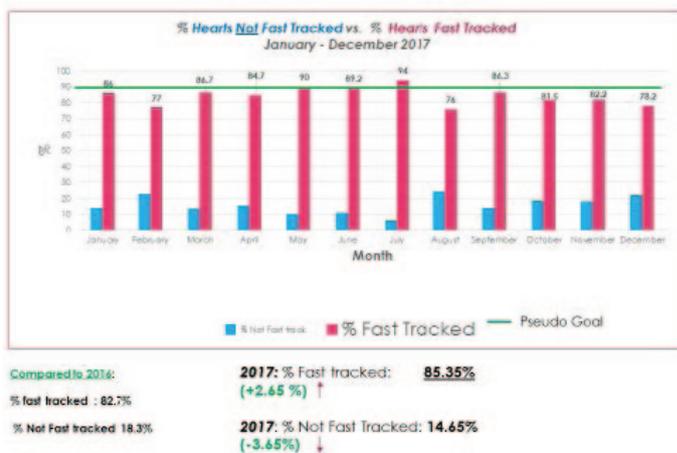


Figure 3. The chart reflects the amount of fast trackable hearts monthly for 2017. Compared to 2016 the team is fast tracking more open hearts and extubating more hearts within the 6-hour window.

The bedside PA, RN and RRT pre-weaning criteria

Post-operative ECG shows no ischemia. Post-operative CXR reviewed & no significant interventions are required. Acceptable post-operative ABG Arterial pH 7.25-7.50, S_aO₂ greater than 92% on F_IO₂ of 40% or less, P_aCO₂ 45 or less). PEEP at 8 H₂O or less. Minute ventilation 10 L/min or less. Stable hemodynamics (MAP 65 mmHg or greater than, CI 2.0 or greater than) without need for high dose inotropic/vasoactive support.

Core Temp 36.0°C or greater than. Patient demonstrates signs of awakening from anesthesia & follows simple voice commands.

Respiratory Therapy and the Ventilation protocol

Upon arrival of the patient to the intensive care unit, respiratory therapy initiates a mechanical ventilation protocol intended to aid in stabilizing the patient post-operatively and promoting a safe and timely extubation. Once the patient is cleared by the PA-C and the RN, then communication is made to RRT to wean the ventilator support in attempt to liberate the patient from mechanical ventilation support. Respiratory care observes the patient. After 30 minutes of weaning, communication is made by the RRT, PA and RN. The decision is made together to whether or extubation is appropriate at this time. If extubation is approved, then the patient is liberated from ventilator support by the RRT and RN. Post-liberation, the patient is placed on to a nasal cannula at a flow rate of 4-6 lpm.

The goal has is to have our open-heart patients extubated within a 6-hour window to compete with national standards. We have two sample populations: 1. fast trackable and 2. non-fast trackable. Those open hearts that were fast track eligible, but not extubated within 6 hours are evaluated by anesthesia, respiratory therapy, and nursing. A drill down of the patient's chart is made to evaluate to note any issues with anesthesia in the operating room, respiratory therapy and mechanical ventilation, RNs and bedside reversal and sedation. Together a conclusion is made, and an improvement is suggested.

Results 2016 vs 2017

For 2016, the first full year of the fast track protocol, 82.7% of the open hearts were deemed fast trackable. Our goal was to have 85% of the fast track open hearts extubated within the 6-hour window. The team exceeded the set goal and achieved 87% in 6 hours. The mean ventilation hours for 2016 were 4.49

Continued on page 62...

The Benefits of Forced Oscillation Technique (FOT) as a Tool for Asthma Diagnosis

Chris Campbell

Finding better and more reliable tools for diagnosing and controlling asthma is of paramount importance to medical professionals.

Spirometry is commonly used by clinicians, but Dr Charlotte Heijkenskjold of Uppsala University in Sweden and colleagues conducted a comprehensive study that looked at how that technique compared with using Forced Oscillation Technique (FOT).

Diagnosing asthma can be tricky because of the strain devices put on the patient to get a good test. Asthma as a chronic inflammatory disease is, in clinical practice, primarily defined by demonstration of impaired and reversible lung function, assessed using spirometry.¹ Forced expiratory volume in one-second (FEV1) is a measure of primarily proximal airway status and is dependent on vigorous and rapid exhalation. A good evaluation of FEV1/FVC is dependent on complete exhalation.

Getting that “complete exhalation” — according to Dr Heijkenskjold’s study — requires both highly skilled staff and a “motivated subject.” Getting the second requirement is made even more difficult when it involves the tiny airways of children.²

According to this Swedish study — entitled *Overall and Peripheral Lung Function Assessment by Spirometry and Forced Oscillation Technique in Relation to Asthma Diagnosis and Control* — the clinical utility of FOT measurements is justified, with the authors providing insightful information about how FOT parameters contribute to asthma diagnosis and asthma control evaluation, in comparison with other non-invasive tools like spirometry.

Introduction

The study authors describe the connection between inflammation in peripheral airways and uncontrolled asthma — and the background of FOT.

“Inflammation in peripheral airways (internal diameter < 2 mm) has been highlighted as an important aspect of asthma.³⁻⁶ Several studies indicate that involvement of the peripheral airways is

related to uncontrolled asthma.⁷⁻¹⁰ Alveolar nitric oxide (NO), an estimate derived from mathematical modelling of exhaled NO at different exhalation flow rates, has been proposed as a marker of peripheral airway inflammation and has been reported to be elevated in disorders with alveolar inflammation, such as allergic alveolitis.¹¹

“Forced oscillation technique (FOT) was originally described by Dubois et al.¹² The technique allows for less effort-dependent lung function testing compared with spirometry. Forced oscillometry only requires tidal breathing and is therefore easier to apply in young children and individuals with difficulties in active cooperation. With the use of oscillations of different frequencies applied to the airways through the mouth during tidal breathing, the airway impedance is calculated from the resultant pressure and flow signals and further divided into measures of total respiratory resistance and reactance for each frequency.¹³

“Numerous devices and oscillatory signal types are used. FOT initially used single sinusoidal sound waves, followed by several technical developments, and further the FOT using pseudorandom noise signal (a mixture of several sinusoidal waveforms) and signal pulses (consisting of square wave impulses, referred to as impulse oscillometry [IOS]) have been developed. Due to previous commercial availability of equipment, most of the recent studies in asthma are based on IOS methodology. However, several commercial devices for multifrequency FOT now exist. Beside technical and computational differences between forced oscillometry by IOS and FOT methodologies, the values yielded are similar but not identical.¹⁴ The IOS over FOT has improved signal-to-noise characteristics, but offers a slightly inferior temporal resolution. IOS also produces pulses of pressure waves that may be uncomfortable for the patient.¹⁵

“Forced oscillometry has been used to demonstrate airway obstruction and response to bronchodilation and challenge tests in asthma.¹⁶⁻¹⁹ There is evidence that this method is more sensitive than spirometry in asthma, but also that it has greater variability, especially with regard to reactance measures.^{20,21} Forced oscillometry can assess both overall and peripheral airway mechanics by utilizing low frequencies that travel all the way to the small airways and, thus, reflect the whole airway tree and high frequencies that travel only proximally, mainly reflecting central airways. Studies have presented data on associations between forced oscillometry values thought to

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reflect distal airway pathology and clinical asthma outcomes in both children and adults.^{7,22-26} Further, an association between forced oscillometry values reflecting peripheral airways and markers of peripheral airway inflammation has been indicated in adult asthma.²⁷

“The primary aim of this study was to compare the value of spirometry and FOT in relation to asthma diagnosis and disease control. A secondary aim was to compare spirometry, on the one hand, and FOT, on the other hand, in relation to airway inflammation, assessed by exhaled and alveolar NO in asthmatic subjects.”

Study Methods

The study authors used the Resmon Pro FOT device, with FOT measurements performed according to the manufacturer's instruction, using a specialized tongue-positioning mouthpiece, during one 10-breaths period that followed after approximately 10 s customization breathing into the device.

According to the study's methods section, “classic spirometry is effort dependent and of limited value in assessing small airways. Peripheral airway involvement, and relation to poor control, in asthma, has been highlighted recently. Forced oscillation technique (FOT) offers an effort-independent assessment of overall and peripheral lung mechanics. We studied the association between lung function variables, obtained either by spirometry or multifrequency (5, 11 and 19 Hz) FOT, and asthma diagnosis and control.

“Spirometry measures, resistance at 5 (R5) and 19 Hz (R19), reactance at 5 Hz (X5), resonant frequency (fres), resistance difference between 5-19 Hz (R5-R19) and Asthma Control Test scores were determined in 234 asthmatic and 60 healthy subjects (aged 13-39 years). We used standardized lung function variables in logistic regression analyses, unadjusted and adjusted for age, height, gender and weight.”²⁸⁻²⁹

Subjects responded to questions regarding asthma symptoms in the preceding 12 months. The degree of asthma control was assessed through the asthma control test (ACT).³⁰ Uncontrolled asthma was defined as an ACT score <20. The subjects were asked to recall if any exacerbation, defined as worsening of asthma symptoms, had occurred during the preceding year.

Lung function tests were carried out by experienced research nurses. Flow-volume curves were obtained, in accordance with the American Thoracic Society recommendations,³¹ using a Masterscope spirometer (Jaeger Master, Hoechberg, Würzburg, Germany). Exhaled NO was measured in accordance with the American Thoracic Society/European Respiratory Society recommendations with NIOX Flex (Aerocrine AB, Solna, Sweden).³² Measurements of exhaled NO were performed as standardized exhaled NO at 50 mL/s (FeNO₅₀), and at 100, 200 and 300 mL/s in random order, as previously described.²⁸ Alveolar and central airway contributions to exhaled NO were calculated using the slope-intercept model based on the NO measurements at 100-300 mL/s,³³ and model compliers were defined with a Pearson correlation coefficient (r) between NO output and expiratory flow ≥ 0.80 , as previously described by Mahut et al.³⁴ Data from 14 (6.1%) asthmatics were not compliant with the slope-intercept model by this prerequisite³⁵ and were not used for the analysis of associations between alveolar NO and lung

function variables. Unadjusted alveolar NO was used in analysis due to conflicting data on the relevance of existing adjustment algorithms in asthmatic subjects with varying disease severity and control.³⁵

IgE against a mix of aeroallergens (grass, tree and weed pollen, animal, mite and mould allergens) (Phadiatop, Immunodiagnosics Thermo Fisher Scientific, Uppsala, Sweden)³⁶ was measured in all but three subjects. Subjects were defined as atopic if they had IgE antibodies against this mix ≥ 0.35 kU/L.

Results

According to the study authors, the results included “lower FEV1/FVC (OR [95% CI] 0.47 [0.32, 0.69]) and FEF₅₀ (0.62 [0.46, 0.85]) per standard deviation increase, and higher R5 (3.31 [1.95, 5.62]) and R19 (2.54 [1.65, 3.91]) were associated with asthma diagnosis. Independent predictive effects of FEV1/FVC and R5 or R19, respectively, were found for asthma diagnosis. Lower FEV1/FVC and altered peripheral FOT measures (X5, fres and R5-R19) were associated with uncontrolled asthma (P-values < .05).

Discussion

The study authors found that FOT provided a significant amount of information about patients.

“The main results of the present study were that lung function measurements by FOT gave at least as much information as did spirometry measures in discriminating, on a group level, asthmatic individuals from healthy controls. Also, FOT measures reflecting peripheral engagement were associated with asthma control. FEV1/FVC was the spirometric variable that offered best information with regard to both asthma diagnosis and level of control. Among FOT variables, FOT resistance measures were most strongly associated with asthma diagnosis, and this information was also independent to that from spirometry. A negative association was found between exhaled nitric oxide (NO) and FOT reactance in asthmatic individuals. In this sample of predominantly well-controlled asthmatic patients, the resistance measures from FOT gave at least as much information as the FEV1/FVC ratio with regard to a likelihood of asthma.”

The study authors made a special note about good results found in patients who were not capable of being tested by spirometry.

“These results are in line with previous studies on bronchodilator change in FOT resistance measures and spirometry in children^{37,38} and adults³⁹ and support a potential use of FOT in asthma diagnosis and management, especially in patients not capable of acceptable spirometry manoeuvres. Independent information for both FEV1/FVC and FOT resistance measures with regard to having asthma was found, and to the best of our knowledge, this has not been previously reported. However, it is a plausible finding, because the information from these two different methods of assessing lung function is regarded as complementary rather than interchangeable.”⁴¹⁻⁴³

“Altered FOT variables, reflecting small airways, were reported recently by Hafez et al.⁴⁰ for stable asthmatic subjects with decreased lung function (mean FEV1 62% predicted) compared with healthy controls. The fact that most asthmatic subjects in our study had well-controlled asthma and normal FEV1 at baseline might explain the lack of difference in the FOT peripheral measures after adjustments.”

The study also discussed the comparison of results between adults and children.

“Lack of asthma control related to decreased FEV1/FVC and altered FOT variables representing peripheral engagement (X5, R5-R19 and fres). In children 6-17 years, Shi et al.^{37,22} presented associations between oscillometry parameters reflecting distal airway pathology and level of asthma control, and also the risk of losing asthma control. Similar associations in adults have been reported by Takeda et al.,²³ who presented an association between lower X5 and loss of asthma control, and also an association between R5-R20 and asthma control.^{43,44} However, Gonem et al.⁴⁵ found no correlation between small airway indices and asthma control. An association between small airways’ FOT variables and asthma control is potentially clinically interesting as the disease process in small airways might not be controlled by conventional ICS treatment, and the FOT pattern of peripheral airway involvement might contribute as an indicator for a therapeutic trial with an extrafine drug formulation inhaler.^{25,46}”

“With regard to the relationship between lung function and airway inflammation, a more negative X5 associated in asthmatic individuals with higher FeNO50, a finding which is in line with previous studies.^{27,47} Classic lung function did not associate with FeNO50, and this corroborates the findings from a recent large study in adults,⁴⁸ but contradicts our previous findings.³⁵ The strength of the present study is that it is one of the largest studies to date to compare FOT and spirometry in both children and adults.”

Conclusion

The study authors concluded that “resistance FOT measures were equally informative as spirometry, related to asthma diagnosis, and, furthermore, offered additive information to FEV1/FVC, supporting a complementary role for FOT. Asthma control was related to FOT measures of peripheral airways, suggesting a potential use in identifying such involvement ... this information appears to be additive to that from standard spirometry in relation to asthma diagnosis.”

While the authors only suggested a supplementary role for FOT, based on their results, stand alone FOT is even better than spirometry in terms of effect size and reliability.

One comment from the study authors was that it might “be suggested that FOT measurements could have added clinical value, for example when spirometry is normal but a clinical suspicion remains.”

The study authors ended with a recommendation for further exploration of this technique.

“To establish the clinical value on individual basis and relevant cut-offs, there is a need for further studies and relevant reference values for the FOT measurements.”

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The Benefits of NIV-NAVA Compared to NIMV

Chris Campbell

When it comes to modes of mechanical ventilation, neurally adjusted ventilatory assist (NAVA) is relatively new. NAVA assists the patient in proportion to the respiratory effort based on the detection of the electrical activity of the diaphragm (Edi) by an array of electrodes built into a modified feeding tube. The Edi is translated into proportional increases in airway pressure in synchrony with, and in proportion to, the patient's respiratory effort. This means patients initiate their own breaths and regulate their own peak inspiratory pressures (PIPs) and inspiratory times (Ti). According to a study by staff at the department of pediatrics at the University of California, the benefits of NAVA are quite significant.

"NAVA, therefore, represents a paradigm shift in ventilatory management, as the standard ventilator settings used in common practice are not used during NAVA," wrote the authors of the research study, *Feasibility and Physiological Effects of Noninvasive Neurally Adjusted Ventilatory Assist in Preterm Infants*.

In the study, the team tested NAVA on infants to see if it was a safe alternative mode of noninvasive support.

NAVA Testing

In the study, the authors outlined a history of how NAVA has been studied in the past, including its origins with a certain animal that had suffered lung injury.

"The literature has recently been reviewed for older infants¹ and newborns,² and practical application has been described by a group with the largest neonatal experience to date.³ The physiological effects of NAVA have been mainly described in intubated patients. In a retrospective study in intubated preterm infants, there was a reduction in PIP, FiO₂, and arterial PCO₂ (in infants with baseline PCO₂>45) on NAVA compared with those on synchronized intermittent mandatory ventilation (SIMV).⁴ These authors also performed a prospective, randomized crossover trial⁵ that showed a reduction in PIP, FiO₂, transcutaneous PCO₂ (PtcCO₂), peak Edi, and respiratory rate on NAVA compared with those on pressure support ventilation (PS). The reduction in the PIP but not in the FiO₂ was confirmed in two randomized crossover studies of intubated preterm infants comparing NAVA with SIMV with PS,⁶ and NAVA with IMV or high-frequency oscillatory ventilation.⁷ The effectiveness of NIV-NAVA was first demonstrated in rabbits.⁸ The first report of

NIV-NAVA in preterm infants was a study performed immediately after extubation⁹ that demonstrated an excellent correlation between the PIP and peak Edi in infants both when intubated and after they were extubated, with no correlation between the PIP and Edi on PS. A large clinical experience suggests that NIV-NAVA reduces the need for invasive ventilation.² The first systematic study of NIV-NAVA was a randomized crossover study in infants immediately after extubation that demonstrated a reduction in PIP but not in FiO₂ on NIV-NAVA vs. NIV-PS, significantly reduced trigger delay, and asynchrony events, even in the presence of large air leaks.¹⁰

"We performed a pilot feasibility study in infants on various modes of noninvasive support to introduce NIV-NAVA to our practice. We were able to lower the PIP and FiO₂ in a subset of these infants during NIV-NAVA compared with nasal intermittent mandatory ventilation (NIMV). The resulting data were used to design a randomized, crossover observational study to test the hypothesis that NIV-NAVA could reduce the PIP needed on NIMV while supporting the infant on the same mean airway pressure and overall gas exchange, as determined by pulse oximetry and PtcCO₂. During both studies, we analyzed detailed recordings of electrocardiogram, oxygen saturation, PtcCO₂, and infant and caretaker movement using an Acoustic Respiratory Movement Sensor (ARMS). Our secondary outcomes were a comparison of the FiO₂ required to maintain the oxygen saturation in a target range, the character of episodes of desaturation, and infant comfort as reflected in the phasic Edi and the measurements of infant and caretaker movement, as these data have not been described. We chose to study noninvasive support, as it represented the majority of ventilatory assistance in our Neonatal Intensive Care Unit and it had the greatest potential to help neonates recover from respiratory distress syndrome without the need for intubation."

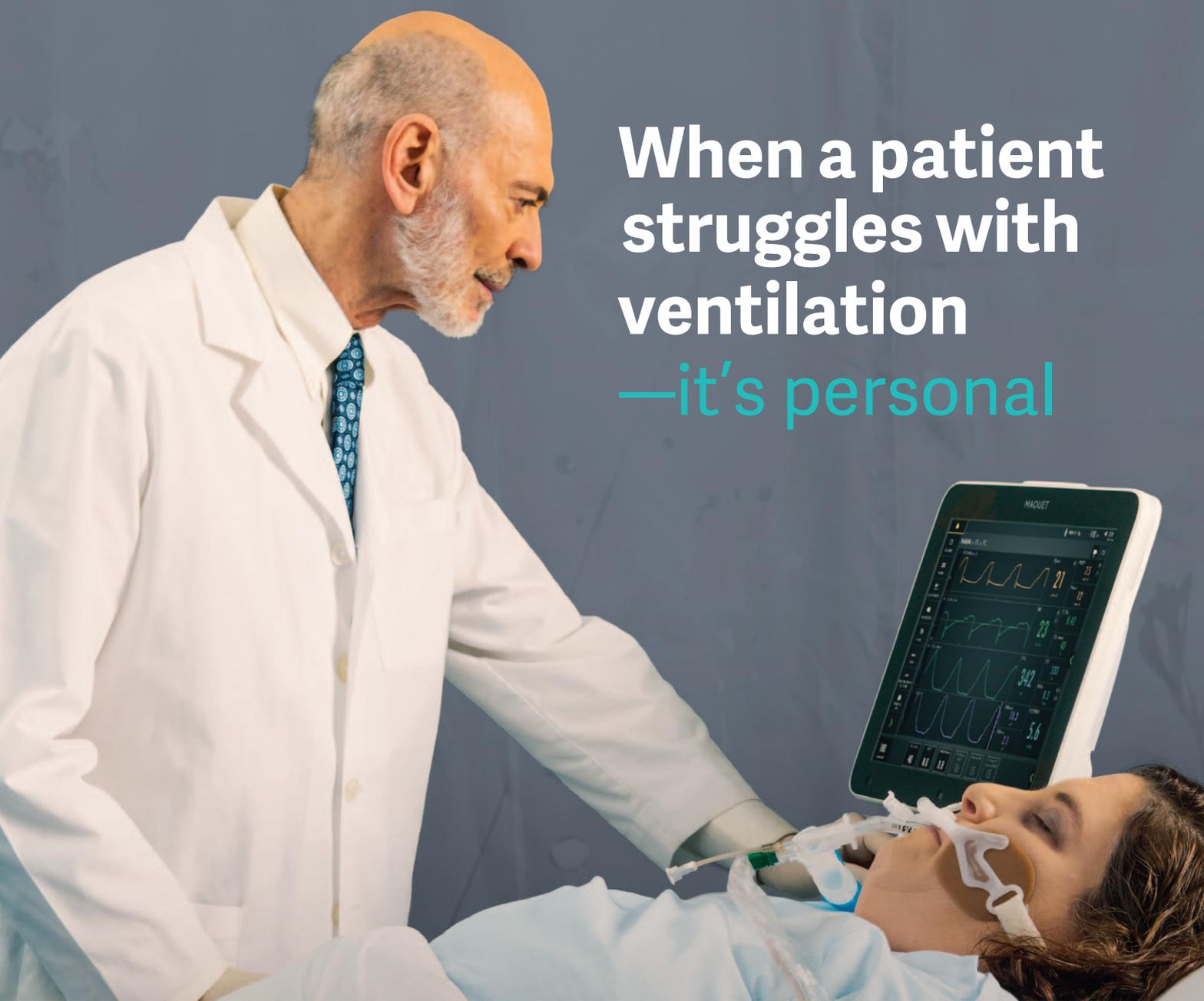
Study Methods

The pilot study was performed between October 2012 and November 2014, with a subsequent randomized observational study performed between August 2014 and March 2016. Both studies were approved by the Institutional Review Board of the University of California, San Diego under separate protocols. Informed, written parental consent was obtained prior to enrollment.

"Our pilot study was performed in 11 preterm infants, ranging in study weights of 840–2,200 g, who were on NCPAP, NIMV, or high-flow nasal cannula," the authors wrote. "We applied NIV-

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NAVA for 2–4 h on each of 1–5 days during which time the NAVA catheters were in place, and compared the infants' physiological response to NIV-NAVA with that of the other methods. We found that we were able to reduce the PIP of $33 \pm 12\%$, ($P < 0.01$, $N = 10$ recordings) in six infants on NIMV. From this limited data set, a power analysis indicated that this reduction could be verified with 14 crossovers in seven infants ($\alpha = 0.05$, $\beta = 0.8$). We chose to study each infant on 2 days to produce data with more generalizability. We also observed that episodes of desaturation were frequently caused by handling of the infant; so this study was coordinated with the routine nursing care to eliminate handling the infants unless necessary during the NIV-NAVA or NIMV recording periods. Premature infants were eligible for enrollment in the randomized observational study if they were on NIMV and considered clinically stable by the medical team. Infants were excluded if they had congenital airway anomalies, congenital heart disease, neuromuscular disease, feeding intolerance, or gastric or esophageal pathology.

"We compared the mean value of the PIP, saturation histogram data, frequency, depth, and length of episodes of desaturations, peak, tonic and phasic Edi, $PtcCO_2$, and infant and caretaker movement from the recording periods in each crossover by the paired t-test or rank-sum test in the case of data that were not normally distributed. The timing intervals were averaged for breaths in each mode in each recording period and compared with their corresponding average within each study day between NIV-NAVA and unassisted breaths by the paired t-test or rank-sum test if the data were not normally distributed."

Results

The authors noted the ease that nurses had in using the device, even on such tiny patients.

"We found that nurses, respiratory therapists, and physicians could easily place the Edi catheter in the appropriate position using the positioning window on the Servo-i ventilator. The total time that the Edi catheter was in place for the pilot and randomized studies was 81 patient days. There were no episodes of gastric distention or suctioning malfunction, and Edi catheter did not require repositioning during the time it was in place in both studies."

The authors also noted that nurses and parents of the infants being tested were pleased with the NAVA results.

"Both nurses and parents of infants subjectively felt that the infants were more comfortable on NIV-NAVA than on NIMV, and fought the ventilator less. This was corroborated by significant reductions in infant movement ($-42 \pm 9\%$, $P < 0.01$) and caretaker movement ($-29 \pm 8\%$, $P < 0.01$) on NIV-NAVA. Caretaker movement was detected in $< 1.2\%$ of the recording times, indicating that there was little handling of the infants during the recordings. There were no differences in the mean heart rates between NIMV and NIV-NAVA."

According to the study, the NAVA catheter was used for 81 patient days without complications. NIV-NAVA produced significant reductions (as a percentage of measurements on NIMV) in the following: PIP, 13% FiO_2 , 13% frequency of desaturations, 42% length of desaturations, 32% and phasic Edi, 19%. Infant movement and caretaker movement were reduced by 42% and 27%, respectively. Neural inspiratory time was increased by 39 ms on NIV-NAVA, possibly due to Head's paradoxical reflex.

"We have demonstrated the feasibility of NIV-NAVA with a substantial experience of 81 patient days," the authors wrote. "The Edi catheter could be placed by the nursing, respiratory therapy, and physician staff with limited experience. With the change to NIV-NAVA, we were able to significantly reduce the PIP and FiO_2 at the same level of gas exchange and mean airway pressure. Short respiratory pauses were reliably detected, and backup breaths were delivered that resulted in a reduction in the frequency and duration of episodes of desaturation. The ventilator returned immediately back to the NAVA mode after providing backup breaths. Infants on NIV-NAVA appeared more comfortable, and had less movement and caretaker intervention, as quantified by the ARMS."

In conclusion, the authors wrote that the "improvements in oxygenation at lower levels of support and the reduction in the frequency and severity of episodes of desaturation, if sustained on NIV-NAVA, could make a difference in the long-term outcomes of BPD or retinopathy of prematurity.

"The safety of NIV-NAVA and its possible longer-term physiological benefits make it a feasible alternate therapy to all current modalities of noninvasive support. A large, randomized clinical trial is needed to determine the effect of NIV-NAVA on important long-term outcomes ... "NIV-NAVA was a safe, alternative mode of noninvasive support that produced beneficial short-term physiological effects, especially compared with NIMV."

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Is BiLevel the 'Holy Grail' of Non-Invasive Ventilatory Support or Overrated Therapy?

Steven C LeCroy, MA, CRT, EMT-P

The Holy Grail is the subject of numerous myths and legends, which makes it difficult for scholars to distinguish fact from fiction. Legends hold that the Grail had the power to heal all wounds, deliver eternal youth and grant everlasting happiness. If you listen to some clinicians BiLevel CPAP (Continuous Positive Airway Pressure) therapy is akin to the Holy Grail, with maybe the exception of everlasting happiness. For the purposes of this article to avoid the debate on the name, CPAP is defined as continuous positive airway pressure therapy with a single pressure. While BiLevel is continuous positive airway pressure therapy with two levels of pressure. Both therapies have their detractors and proponents. But when we get right down to where the rubber meets the road, what we really want to know: Is BiLevel better than CPAP or vice versa? What pressures should be used? What types of patients would respond better to BiLevel or CPAP? Does either therapy improve outcomes or reduce length stay? For those that are non-clinical, can either therapy save money? The goal of this article is to look behind the curtain and see if the shift to BiLevel makes a difference.

BiLevel is often referred to as BiPAP™ (BiLevel Positive Airway Pressure – Respironics) or VPAP™ (Variable Positive Airway Pressure – Resmed). For this article the terms BiLevel and CPAP will be used based on the definitions provided earlier. With that said, I don't think BiLevel is better than CPAP, it's just different therapy. BiLevel may be more effective for some patients or the preferred treatment for some patients with difficulty breathing, but not better. The idea of better came from the routine practice of many physicians to automatically change therapy from CPAP to BiLevel when a patient arrives to the hospital by EMS or is admitted. Generally, EMS agencies do not have BiLevel capabilities and are using CPAP for all difficulty breathing patients regardless of the underlying cause. During the 2018 National Association of EMS Physicians conference, (NAEMSP), I asked several EMS physicians if they routinely change therapy

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from CPAP to BiLevel when patients arrive by EMS and the answer was a resounding yes. When I pointed out that current research does not strongly support one over the other, each one said in their experience patients did better on BiLevel. However, when Respiratory Therapists were asked the same question, most felt the doctors were overutilizing BiLevel. How's that for a conundrum? If BiLevel is better why doesn't EMS use BiLevel? If it's not better why do physicians routinely change therapy? The most likely reason EMS does not use BiLevel is the cost. Currently, there are no disposable BiLevel devices and BiLevel ventilators come with a big price tag. A disposable CPAP device can be purchased for less than \$50 and can be left with the patient, no delays, no cleaning and simple to use. As far as physicians routinely using BiLevel over CPAP, I believe some anecdotally think it's better, others think that by the time the patient gets to the ER they are tired and need the extra help BiLevel provides and some may not know the difference.

If we follow the thinking that the patient is tiring or having trouble doing the work, then the obvious question would be which therapy is non-invasive ventilation (NIV)? There are plenty of papers that state CPAP is NIV and there are plenty of papers that say it's not. I for one believe it's not. CPAP is for a spontaneously breathing patient who can still do the work, but would benefit if the work was easier. Many of these patients have an oxygenation issue and are best described as hypoxic difficulty breathing patients. BiLevel is generally for spontaneously breathing patients who need some help doing the work best described as a hypercapnic difficulty breathing patients. When BiLevel devices cycle pressure from low (expiratory pressure or EPAP) to high (inspiratory pressure or IPAP), that kick in pressure helps the patient inhale making it a form of NIV. Some BiLevel devices also offer a backup rate often described as a spontaneous and time BiLevel mode providing a breath if the patient becomes apneic, this capability is not seen with most CPAP devices. So, instead of pigeonholing a patient under difficulty breathing why not assess which patients are hypoxic or hypercapnic or both. The best solution, especially prehospital or when there is a shortage of BiLevel ventilators might be a disposable device that offers both BiLevel and CPAP.

What's a beneficial starting pressure? I don't believe there is a universal answer when it comes to using CPAP or BiLevel for difficulty breathing. When utilizing CPAP I think the best approach is to start low and work your way up, subsequently there can be negative effects of increased airway pressure, such as a drop in blood pressure or an increase in the work of

breathing. Using the lowest pressure that improves the patient's respiratory status should be the goal. In the pre-hospital setting research indicates the maximum pressure should be 10 cmH₂O. In the hospital higher pressures can be used due to a more controlled setting. With BiLevel the same thinking applies, the lowest pressure that improves the patient's respiratory status. Good initial BiLevel starting pressures would be 10 cmH₂O for the inspiratory pressure (IPAP) and 5 cmH₂O for the expiratory pressure (EPAP). These numbers can always be adjusted based on patient assessment. Nevertheless, the difference between the IPAP and the EPAP pressures often referred to as pressure support should always be at least 5 cmH₂O. Some of the advanced BiLevel devices offer automatic settings that adjust pressure levels according to patient need.

CPAP in general has been shown to reduce intubations, admissions to critical care units, and, consequently, a reduction in length of stay. Most of the studies that report outcomes from CPAP therapy do not differentiate between BiLevel and CPAP. Anecdotal evidence would indicate that BiLevel improves outcomes when compared to CPAP. Apart from the 1997 study by Mehta (1997 Critical Care Medicine) that stated, "The higher rate of myocardial infarctions associated with the use of bilevel positive airway pressure highlights the need for further studies". All other studies concluded the number of myocardial infarctions was similar in CPAP and Bilevel therapy groups. The difficulty would be to get a study approved by an institutional review board (IRB) when physicians believe one therapy is better than the other.

So, back to the basic question. Does BiLevel therapy produce a better outcome than CPAP therapy? The popular opinion appears to be yes, but what we don't see is the supporting documentation. Most everyone agrees that positive pressure therapy works. What everyone doesn't agree on is which form of therapy works best. I know one pulmonologist that believes all patients with difficulty breathing should be CPAP candidates. What he doesn't say is which type. I've never been a fan of always and never when it comes to medicine. A better sequence of questions would be: Should the appropriate therapy be determined based on patient assessment? Is the patient hypoxic or hypercapnic or both? Do we understand the pathophysiology of different medical conditions that may benefit from not only positive pressure, but pressure delivered in different ways? The jury is still out on BiLevel making a difference, but with advances in technology and further studies, we may soon have our answer.

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Focus on Bronchiectasis/COPD Overlap: An Under-Recognized But Critically Important Condition

Gary Hansen, PhD

Former “Orphan Disease” Grows in Recognition

Non-cystic fibrosis bronchiectasis (NCFB)¹ is an important disease that remains largely unknown. Once thought to be a rare “orphan” condition—merely the aftermath of infectious diseases that are now readily treated—emerging evidence now shows that NCFB is far more common than originally believed and is closely associated with another better known major respiratory health threat—COPD.³ Defined as the thickening and enlargement of the airways resulting from chronic inflammation, bronchiectasis damages normal airway clearance mechanisms and results in the accumulation of excess secretions. As a result, patients face chronic cough, excess sputum production, and a recurring cycle of hospitalizations.² Appropriate diagnosis and treatment are key to improving quality of life and reducing the need for expensive medical care. Specifically, airway clearance therapy directly addresses the problem of purulent sputum retained in the airways and by “emptying the Petri dish” can help to reduce the risk of future exacerbations without risking exposure to the negative effects of long-term or rotating antibiotics.⁴

Bronchiectasis has rightly been called an “orphan with many parents”⁵ because it is the late stage of a number of pulmonary diseases and a disease with a pulmonary component. Among these are infectious diseases such as tuberculosis and nontuberculous mycobacteria (NTM), severe lower respiratory tract infections, chronic aspiration of gastric contents, inhaled foreign objects, and genetic conditions such as cystic fibrosis, alpha-1 antitrypsin deficiency, and primary ciliary dyskinesia. Autoimmune disorders, such as rheumatoid arthritis, sarcoidosis, and granulomatosis with polyangiitis have also been linked to NCFB. Additionally, diseases that affect the immune system, for instance, HIV and common variable immunodeficiency, may lead to chronic or recurrent infections resulting in bronchiectasis in the susceptible host. Despite considerable effort, no identifiable cause is found in 30-50 percent of cases.⁶ Once the airways are distended and ciliary transport damaged, a “vicious cycle” will often begin: mucus is retained in the airways becoming a site for bacterial colonization; this in turn provokes an inflammatory response that, if it becomes chronic, causes additional damage.⁷ The progression may be slow or swift depending on a number of factors, but once begun, the patient faces an ongoing cycle of recurring infections, resulting in reduction in lung function and quality of life, and the likelihood of ongoing medical care.

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Recognizing Bronchiectasis²

- Chronic productive cough
- Chronic mucus hypersecretion
- Chronic antibiotic use
- Frequent hospitalizations
- Reduced quality of life

The process is irreversible and there is no known cure—fortunately, appropriate care can substantially improve the lives of affected patients.

While bronchiectasis may be found at any age, it is most often a disease of middle-age and older. The profile of a patient with bronchiectasis is in many ways similar to that of chronic bronchitis.⁸ Affected patients often have a chronic productive cough for more than three months of the year along with copious sputum production that is difficult to fully clear. They may have multiple unsuccessful attempts with airway clearance techniques. As a result, their quality of life is often poor due to cough, shortness of breath, and fatigue.⁹ Typically, by the time they are diagnosed, patients will have received multiple courses of antibiotics punctuated with frequent exacerbations, often requiring hospitalizations. The gold standard for bronchiectasis diagnosis is the high-resolution CT scan, which can show varying degrees of bronchial wall thickening and dilation of the airways.² It is important to note that patients may have radiographic evidence of bronchiectasis but show no symptoms; indeed, they may be stable in the condition for years. However, the airway damage may develop into significant symptoms at any time given the appropriate trigger.

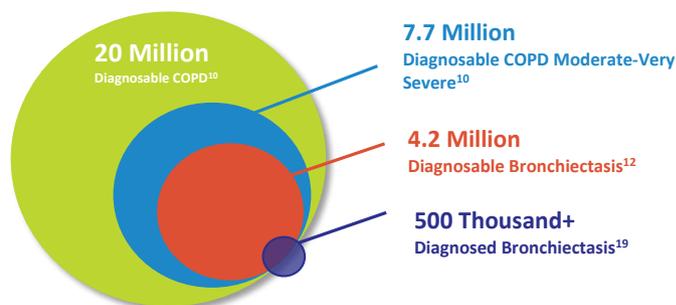


Figure 1 Estimates of the prevalence of diagnosable COPD, diagnosable bronchiectasis, and diagnosed bronchiectasis.

The COPD Connection

Today a large and growing number of patients with COPD also have been diagnosed with bronchiectasis. More than 20 million people in the US live with COPD¹⁰; of these more than four million patients may be affected by bronchiectasis, yet only about 500,000 have been diagnosed with the condition, a number rising at an annual rate of 8.7 percent, most likely due to increased awareness and surveillance of the disease.¹¹ A recent meta-analysis of available data found that over 50 percent of patients with moderate-to-severe COPD also have evidence of bronchiectasis.¹² The causes, treatments, and relationships between comorbid conditions within COPD are controversial and a subject of intensive research. The evidence has led some researchers to propose a “COPD-bronchiectasis overlap syndrome,”¹³ while this concept is still debatable.¹⁴ Nonetheless, COPD may be considered a possible cause of bronchiectasis¹⁵, and bronchiectasis is certainly an exacerbating factor in COPD.¹⁶

It has long been known that COPD patients often experience a cycle of exacerbation followed by temporary recovery. More recently, a study by Suissa et al has shown that exacerbations follow a distinct pattern: after the first event, each subsequent exacerbation follows within a shorter time and tends to be more severe than the last.¹⁷ In this study, risk of a severe exacerbation increased three times after the first exacerbation, and 24 times after the tenth. This finding emphasizes the importance of early intervention in recognizing and treating the disease, particularly when combined with bronchiectasis. A recent meta-analysis by Du et al, of 5,329 COPD patients found a greatly increased exacerbation risk due to comorbid COPD with bronchiectasis compared to COPD alone.¹⁸ Moreover, the risk of exacerbations rose almost two times higher, colonization of the lungs four times higher, severe airway obstruction 30 percent higher, and mortality two times higher. It is not surprising that such elevated risks are also associated with higher healthcare costs. A recent study found that compared to COPD alone, COPD + bronchiectasis resulted in 32 percent more hospitalizations and 27 percent higher hospitalization costs.¹⁹ With these issues at stake, there is a clear need to focus on these at-risk patients.

New Guidelines for Treatment

Given that a sizable fraction of COPD patients who are troubled with excess sputum production may harbor bronchiectasis, it seems prudent to evaluate for the condition using a high-resolution CT scan.

Along with bronchodilators and mucolytics, bronchiectasis patients are sometimes treated with long-term antibiotics such as macrolides. While useful in addressing severe exacerbations, long-term use of such drugs raises the risk of antibiotic resistance and side effects such as cardiac complications and hearing loss.⁴ Additionally, a recent study found that bronchiectasis patients are frequently colonized by antibiotic-resistant pathogens.²⁰ Among NCFB patients who received testing, 69 percent had a positive sputum culture; of these, 20 percent were multiply-drug-resistant organisms (MDR) that are also deemed “urgent” or “serious” threats according to the CDC.²¹ MDR organisms are not only difficult to eradicate, but pose a long-term threat to antibiotic stewardship. Therefore, any measure that can reduce the bacterial load in patients’ lungs can be valuable in breaking the vicious cycle of infection that such patients face.¹⁵

New treatment guidelines for bronchiectasis have recently been released by the European Respiratory Society (ERS).⁴ This important report contains a broad survey of available evidence, including drug treatments and a discussion of airway clearance. The ERS guidelines state that “before considering the prescription of long-term antibiotics, general aspects of bronchiectasis management need to be optimized such as airway clearance.” The list of airway clearance methods includes pulmonary physiotherapy, oscillating positive expiratory pressure (PEP) devices and high-frequency chest wall oscillation (HFCWO or “vest therapy”). As a non-pharmacological method for clearing sputum, airway clearance devices are effective, readily accepted by patients, and support antibiotic stewardship.²² Aside from directly addressing the needs of symptomatic patients, airway clearance has been shown to reduce the risk of exacerbations²³ and enhance quality of life.²⁴ A database housing the self-reported outcomes of more than 10,000 bronchiectasis patients shows that after the initiation of vest therapy (inCourage® System, RespirTech, St Paul, Minn.), antibiotic use was reduced by 15 percent and hospitalizations by 59 percent (Figure 2).²⁵

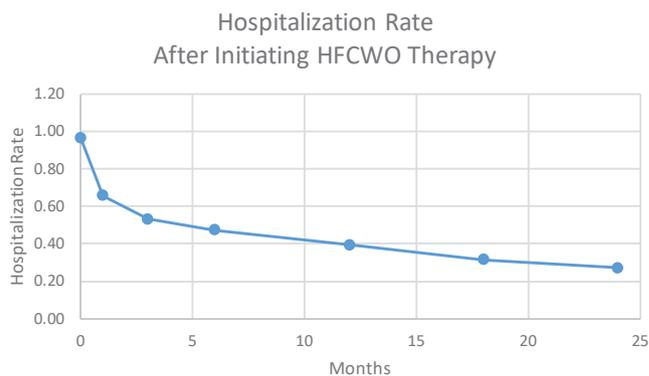


Figure 2 Reduction in hospitalization rate after initiating HFCWO therapy for over 10,000 patients with bronchiectasis.²⁵

In summary, bronchiectasis is a progressive disease of the lungs that facilitates a cycle of exacerbation for affected patients. Under-recognized until recently, it is far more common than previously believed. Combined with COPD, bronchiectasis adds substantial risk of hospitalization and early death. Once bronchiectasis is identified, although irreversible, it can be managed by treating the underlying cause (if identified) with appropriate drug therapy and airway clearance devices.

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Assessment Considerations for PMV[®] Use in the Pediatric Population

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Premature birth is defined as birth before 37 weeks gestation and is the leading cause of death in babies in the US. According to the March of Dimes, for the first time in eight years, the preterm birth rate in United States has increased to 9.63% as reported by the National Center for Health Statistics (NCHS) (2016 Premature Birth Report Card, 2016). These premature infants often face health issues including, but not limited to: respiratory complications, jaundice, retinopathy of prematurity, developmental delays, and gastrointestinal complications. It has been reported by the National Academy of Medicine, that preterm birth costs \$26 billion dollars annually. Due to advances in medical technology and scientific innovation, more of the micro-preemies, those born at less than 26 weeks gestation or less than 800g, and those with congenital abnormalities are surviving but not without frequently facing prolonged medical challenges.

Respiratory support via mechanical ventilation is imperative for children who survive early birth due to the underdevelopment of the respiratory system and risk for development of Bronchopulmonary Dysplasia (BPD). Bronchopulmonary Dysplasia is a form of chronic lung disease that can develop in preterm infants who have been treated with oxygen or positive pressure ventilation. Symptoms of BPD include tachypnea (increased respiratory rate), tachycardia (increased heart rate), frequent desaturations and increased respiratory effort evidenced by any of the following: retractions, grunting, and nasal flaring. This is despite the introduction of surfactant therapy and increased use of noninvasive positive pressure ventilation (Overman, et al, 2013). Many of these infants will require tracheostomy placement due to the need for prolonged mechanical ventilation or the presence of upper airway abnormalities which prohibit successful extubation. Supportive research has stated that early tracheostomy has reduced the occurrence of associated subglottic and tracheal stenosis for children who have had prolonged intubation (Overman, et al, 2013).

Impact of a Tracheostomy

Tracheostomy is the outcome of the tracheotomy procedure that creates an artificial airway in the trachea and redirects airflow, bypassing the patient's upper airway. This procedure is performed by a pediatric surgeon or otolaryngologist. One method for this procedure is to have a vertical incision made

below the level of the vocal folds over the third to fourth cartilage ring (Alladi, et al, 2004), creating a stoma wherein a tracheostomy tube is placed to create the artificial airway. Indications for tracheostomy placement include the need for long-term mechanical ventilation, upper airway obstruction, pulmonary hygiene, and poor secretion management (Abraham, 2003). When looking at the reasons for tracheostomy in 184 infants, 78.8% of those born at extremely low birth weight had more than one reason for tracheostomy placement, including diagnoses such as bronchopulmonary dysplasia, congenital heart defect, subglottic stenosis, respiratory failure, laryngeal and tracheomalacia (Overman, et al, 2013). While tracheostomy placement is often lifesaving, the placement of tracheostomy is not without secondary complications.

Documented complications of tracheostomy placement include tracheal infections, accidental decannulation and obstruction, reduced or absent airway protection, reduced secretion management, swallowing deficits, and reduced ability to produce voice (Abraham, 2003). In children who undergo tracheostomy prior to the development of speech, during infancy or early childhood, the development of oral communication and verbal interaction with their environment may be delayed. Use of a Passy Muir[®] Tracheostomy & Ventilator Speaking and Swallowing Valve (PMV) can aid in the ability to restore airflow through upper airway, which would allow a child to produce a cry and voicing and normalize aspects of language development.

Additionally, the use of the PMV[®] has been documented to improve secretion management, aid in weaning of respiratory support, and improve airway protection responses in both adults and children due to the restoration of upper airway sensation (Sutt, et al, 2015; Blumenfeld, et al, 2011). It has been stated that use of PMV in appropriate candidates less than 2 years of age has resulted in more normal acquisition of vocal exploration and speech development (Engleman & Turnage-Carrier, 1997; Jiang & Morrison, 2003). Considering the positive outcome with PMV use, clinicians working with the pediatric population with a tracheostomy should aim to establish PMV use as soon as medically and clinically appropriate.

Assessment For PMV In Children

Assessment for PMV use in children can create additional challenges for the clinician when compared to evaluation for use in adults. Children, specifically infants and those under the age of 2 years of age or those with developmental delays, are not able to voice on command which would typically be a method used

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with older children or adults during assessment of upper airway patency. When initially assessing with digital occlusion, voicing or attempting to voice is generally used to look for an ability to pass air around the tracheostomy tube and up through the vocal cords. Very young children also cannot articulate feelings of discomfort during PMV trials. Furthermore, in young children who have had a tracheostomy for the majority of their life, they may not be able to complete a more normalized exhalation process and may not be able to coordinate exhalation with phonation. Because volitional voicing is not possible with infants and young children, other considerations have to be used during assessment and treatment. A clinician may have to target this coordination with therapeutic interventions until true voicing can be heard. This is again different when compared to an older child or an adult patient with a tracheostomy who has had prior experience of vocalizing and speaking without the presence of the artificial airway.

Clinical assessment considerations:

When moving toward assessment of the nonverbal or young child, the first step is to complete a thorough review of their medical history and discuss it with the child's medical team to rule out any contraindications for PMV use. Contraindications for PMV use may include, but are not limited to, severe subglottic stenosis, severe tracheomalacia, tracheal edema, bilateral vocal fold paralysis in the adducted position, severely reduced lung compliance, and the presence of an inflated cuff or foam filled cuff tracheostomy tube.

Due to the small size of the pediatric trachea there is a greater risk of airway obstruction. The airway diameter in infants less than 6 months of age is approximately 6mm and grows to 8-11mm by the time a child is approximately 10 years of age. Considering this small tracheal size, even slight congenital or inflammatory obstruction can lead to increased risk of airway obstruction (Alladi, et al, 2004). Therefore, the proper sizing of the diameter of the tracheostomy tube in relation to the size of the child's airway is crucial to adequate airflow through the upper airway and for successful usage of a PMV.

In the pediatric population, both pediatric and neonatal tracheostomy tubes may be used. The difference between the two is length, with the pediatric tube being longer than the neonatal but the inner diameter remaining the same. It is the inner diameter of the tracheostomy tube that is often described when the question is asked "what size tracheostomy tube do they have". Throughout the time that a child may remain

tracheostomized, the size and length of the tracheostomy tube may be modified to accommodate changes in airway due to growth and respiratory support needs. A Pediatric Otolaryngologist can assess the airway and tracheostomy by direct laryngoscopy to determine appropriate size and length. Because of these potential changes, the clinician must continually monitor and evaluate the needs of the child.

Another variable to consider that affects the tracheostomy and potential obstruction in a child's trachea is the presence or absence of a cuff. Placement of the PMV requires full deflation of the cuff, yet, having the added circumference of the deflated cuff material present can reduce airflow and affect the ability to use the Valve. When working on an interdisciplinary team, it is beneficial to attempt to transition a child to a cuffless trach, as soon as medically appropriate, to reduce its impact on the child's transition to Valve use.

Successful Use of the PMV

Successful use of PMV is directly related to the amount of air that will flow around the tracheostomy tube and up through the larynx, nose, and mouth. Variables affecting this airflow include tracheostomy size in relation to patient's tracheal diameter, as well as the presence or absence of any anatomical or structural narrowing (ie subglottic stenosis). One way that assessment of airway patency can be completed is via bronchoscopy; however, this is an invasive procedure that is unable to be conducted in a wide variety of environments and involves many disciplines (Utrarachkij, et al, 2005).

Current standard practice for bedside evaluation for PMV candidacy in pediatrics is to assess upper airway patency via digital occlusion of the tracheal hub. The clinician occludes the hub by lightly placing a gloved fingertip over the end of the trach tube hub. After digital occlusion and with close clinical monitoring, the clinician then waits to hear voicing or listens for upper airway breath sounds, via stethoscope, or by assessing for airflow out through the nose and mouth (ie use of a mirror under the nose to look for fogging is one method). While these assessment measures will demonstrate a clinical measure of airflow, it does not give information to the clinician regarding the amount of exhaled air that is moving up and out through the mouth and nose. Use of spirometry has been documented as an objective measure of upper airway patency; however, the use of spirometry continues to depend on the child's ability to follow commands and coordinate breathing into the spirometer, which can be difficult for some of our younger or developmentally disabled patients (Utrarachkij, et al, 2005). The added medical complexity and cognitive limitations of this younger population may make identification of successful and unsuccessful PMV trials difficult to distinguish from each other.

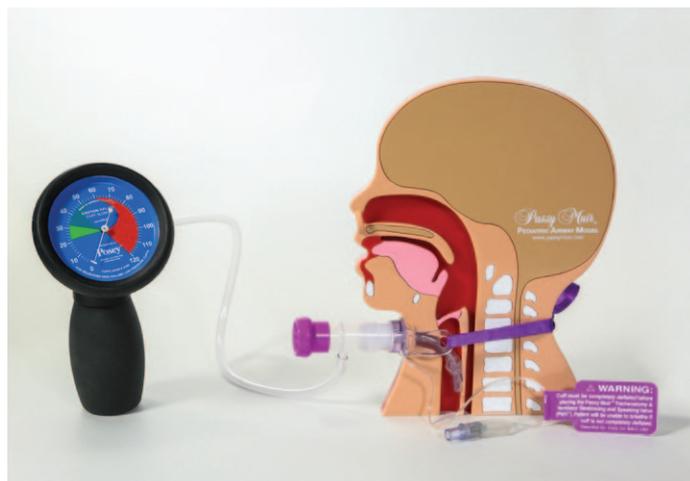
Prior to placement of the PMV, the clinician should make note of the baseline measurements for the infant or child. These would include heart rate, respiratory rate, oxygen saturations, and having a good indication of skin color and respiratory pattern through observation. Once baseline measurements are obtained, one indicator of successful PMV use is with observed adequate voicing. With an infant or young child this may include crying, cooing, babbling, or any other vocalizations. Moreover, the child should be comfortable, without changes in respiratory pattern or increased respiratory effort. During this time, the clinician should not only be monitoring respiratory impact but should be watching the overall state of the child and monitor for changes

in physiological or autonomic indicators such as: heart rate, oxygen saturation, and respiratory rate. Furthermore, clinical observations should be taken in relation to the child's coloring looking for signs of perioral cyanosis and looking for other indicators of decompensation (becoming flushed, sweating, etc.).

Utilization of the PMV is often seen as the first step towards removal of the tracheostomy in a patient who is deemed a candidate for eventual decannulation by their medical team. When a patient achieves wearing of their PMV all waking hours and is on a weaning protocol, the next step is towards capping of the tracheostomy tube. During capping trials, a solid cover is placed on the tracheostomy hub which completely closes off the tracheostomy and normalizes the use of patient's upper airway. As part of the medical team, the clinician will assess for tolerance of tracheostomy capping utilizing a similar protocol as for the PMV assessment. Once a patient is wearing a cap all waking hours, the patient may then be referred to their otolaryngologist or pulmonologist for repeat bronchoscopy and an overnight sleep study to assess for decannulation.

More Options for Objective, Data-Driven Assessment

As we move towards more objective and data driven clinical practice, the question is asked: how can we more instrumentally and objectively assess the status of a child's upper airway when they are non-verbal at the time of evaluation? There is documentation in the literature to support the use of end expiratory pressure (EEP) or transtracheal pressure (TTP) during passive exhalation to non-invasively assess upper airway patency as part of the assessment procedures in the pediatric patient for PMV use (Utrarachkij, et al, 2005). This is accomplished using a pressure manometer attached to the PMV via connection tubing and a Washington Tee adapter, or similar adapter that is then placed onto the tracheal hub.



The manometer provides a reading of pressure at the level of the tracheostomy at the end of the exhalation. Research has shown a positive relationship between children who demonstrate a clinical inability to wear the PMV as judged by change in heart rate, oxygen saturation, report of respiratory difficulties (chest tightness or coughing) or abnormal breathing patterns during a five minute PMV trial and higher TTP measurements of greater than 10cm/H₂O (Utrarachkij, et al, 2005). Furthermore, TTP of < 6cm/H₂O was associated with observed clinical tolerance and easier transition of children to PMV wearing schedules (Buckland, et al 2012; Abraham, 1997, 1995). Research has

shown that TTP up to 10cm/H₂O with successful PMV wearing (Buckland, et al, 2012). It is important to note that these TTP measures are to be completed during passive exhalation, such as phonation; coughing and other more forceful exhalations will result in increased numbers in TTP and will skew the readings. These measurements also must be taken when a child is calm and quiet; play and other activities may increase the numbers. Therefore, when air is purposefully expelled with increased force in order to produce voice or in an attempt to clear the airway or increased due to play or other activities, the manometer pressure reading is not accurate.

Behavioral Factors

An additional factor in PMV usage in children is a behavioral response to the placement of the PMV during assessment and ongoing trials. Children who have undergone tracheotomy at a very early age are often hypersensitive to the feeling of upper airflow through their nose and mouth. For infants and many young children, this may be something that they have not experienced in their lifetime. Due to this, children may demonstrate various clinical presentations that appear as difficulties but require behavioral adjustments. A child may exhibit blowing off the PMV or breath holding, which otherwise may be interpreted as clinical intolerance. The difficulty a clinician faces is determining if these observed symptoms are behavioral or due to reduced upper airway patency or airflow. The presentation of the two can look very similar to the naked eye of the clinician. Engaging in monitoring of TTP can help determine the etiology of the observed behaviors; whereas, if the TTP is < 6cm/H₂O then research has shown that it is less likely that the clinical presentation is due to a structural or anatomical issue.

If it is determined to be behavioral in nature, clinicians working with a pediatric population should engage the child in some desensitization and use distraction or play therapy during PMV trials. Often with young children, the clinician will institute these techniques prior to the initial assessment in order to set the child up for success. By doing so, the clinician may elicit a period of time that a child can demonstrate passive exhalations while wearing the PMV by helping the child become more comfortable and relaxed during the assessment. As previously discussed, transtracheal pressures are most accurately and reliably measured during passive exhalation. By achieving adequate and accurate TTP measurements, the clinician will have a better clinical assessment for use of the PMV.

Troubleshooting

If a child demonstrates elevated TTP, having further assessment completed by a physician and the clinical team to evaluate airway management may assist with improving upper airway patency and use of the PMV. Elevated TTP, in conjunction with laryngoscopy demonstrating poor tracheal lumen fit (tracheostomy tube size within the diameter of the trachea), provides sufficient clinical information to support the need for a change in tracheostomy tube size. Changing the tracheostomy tube size may allow for improved upper airflow in those children without identified structural or anatomical etiology. Reducing the outer diameter of the tracheostomy tube and increasing the space in the tracheal lumen, can improve airflow through the upper airway. This in turn can improve use of the PMV and improve clinical tolerance for wearing the Valve secondary to the increased room around the cannula for airflow to move around the tracheostomy tube and into the upper airway.

When attempting to delineate behavioral response versus structural or anatomical narrowing, as a cause of high transtracheal pressures during PMV placement, getting calm and passive exhalations is key. As previously mentioned, in children this can be difficult. Researchers have investigated the use of TTP monitoring and its place in determining PMV candidacy and tolerance (Bishara, et al, 2016). Bishara, et al (2016) observed nine children wearing their PMV with physiologic parameters including heart rate, respiratory rate, oxygen saturation and end tidal carbon dioxide monitoring taken during waking hours and while sleeping overnight. Preliminary findings from this study found that TTP remained stable in those who demonstrate clinical tolerance of PMV usage when awake and during sleep. While the PMV is not currently recommended for use during sleep, in this study, TTP was measured during sleep to ascertain that the child was completely relaxed. The measurements during sleep assisted with reducing the potential impact of variables such as behavior, aversion, and speech production or crying; thereby allowing the researchers to assess airway patency in isolation. The study results indicated that there were no statistical differences in the monitored variables when wearing the PMV while sleeping as compared to daytime wear, and no identified adverse cardiopulmonary events occurred. These preliminary results suggest that PMV use during sleep may be both safe and beneficial; however, additional investigation is warranted.

Post-Assessment

After assessment of the pediatric patient is completed, if a child demonstrates clinical tolerance of the Valve evidenced by all physiologic parameters remaining stable and TTP pressure of no greater than 10cm/H₂O during passive exhalations, the patient should be started on a wearing schedule based on their behavioral tolerance. This wearing schedule should be advanced until the child reaches the goal of wearing their PMV during all waking hours. During the advancement of the PMV schedule, these children are participating in speech and language therapy with the clinician. Goals of therapy are often focused on advancing language skills, improving functional vocalizations, or cognitive therapy, as needed, based on the child's current and premorbid functioning. Additionally, while research has mixed data on the effects of reducing laryngeal penetration or aspiration in children with tracheostomies (Ongkasuwan, et al, 2014), due to the restoration of upper airflow and improved airway protection via improved cough that is linked to PMV placement (Suiter, et al, 2003), clinicians may consider addressing PMV placement prior to initiating therapeutic feeding goals.

If initial assessment does not indicate that a child is a candidate for Valve use at the time of evaluation, the reason for the difficulty should be considered. If it is due to change in any physiologic parameters previously mentioned or the TTP is consistently above 10cm/H₂O, then the medical team must further assess the options. Another consideration is to monitor for increasing TTP with each exhalation. Changes in physiologic parameters or TTP being high may involve a referral to a pediatric otolaryngologist to assess the airway for any signs of stenosis or narrowing, and for consideration for reduction in the size of the tracheostomy tube.

Summary

Pediatric tracheostomy placement is occurring with greater incidence due to the advancements in medical interventions,

and the increased survival rate of infants who are premature and those with congenital abnormalities. Long term tracheostomy placement has been associated with delayed acquisition of language and social development (Cowell, et al, 2013). Additionally, long term tracheostomy can impact parent-child bonding and the ability of the child's family to know their wants and needs due to the communication impairment (Lieu, et al, 1999). Assessment and usage of PMV is important for the normalization and development of the social and language development of these children and can be seen as a first step towards decannulation. Due to the limited volitional participation of infants and young children, the clinical assessment of pediatric use of the PMV presents with specific challenges that are unlike those observed in the adult population. Airway patency is directly related to the successful wearing of a PMV but is difficult to assess objectively through clinical judgement alone. The use of transtracheal pressure monitoring through manometry is a great asset to the evaluation for PMV use in the pediatric population.

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Multidisciplinary Approach...continued from page 45

hours with a standard deviation of ±0.71 hours. For 2017, the goal was set to have 90% of the fast track eligible open-heart patients to be extubated within the 6 hours. Our results yield that we were close to the goal at 89.7%. Average ventilation hours overall for the hearts was 4.34 hours SD ±1.66 hrs. From March 2015 to January 2018, closed-loop communication amongst the multidisciplinary team yields a 0% re-intubation rate post-extubation despite liberation from mechanical ventilation within 30 minutes post weaning.

Clinical Research Training in an Associate Degree Program

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Abstract

Introduction

Establishing the baccalaureate as the entry-level degree for registered respiratory therapists (RRTs) remains an important objective for the profession of respiratory care. RRTs who earn a baccalaureate degree (BD) would possess enhanced research knowledge and research skills needed for advanced clinical practice. Since the majority of respiratory care graduates currently earn the associate as the entry-level degree, we undertook this study to determine whether sophomores, in an associate degree (AD) program, could acquire fundamental research knowledge and research skills by participating in a first, undergraduate clinical research experience.

Methods

In spite of temporal and spatial limitations inherent in an AD program, sophomores participated in a research experience that included: 1) four weekly didactic sessions, 2) one laboratory session and 3) a 2-day hospital-based clinical research practicum, after which gains in research knowledge and skills were evaluated.

Results

Post-research practicum test scores (mean \pm standard deviation = 75.94 ± 11.86), were significantly ($p = 0.0001$) greater than pre-research practicum test scores (mean \pm standard deviation = 52.81 ± 12.11).

Conclusion

Instituting a first, undergraduate clinical research experience within a respiratory care AD program appears an important educational strategy by which sophomores can acquire fundamental research knowledge and research skills needed to practice evidence-based medicine and implement protocol-guided cardiopulmonary healthcare.

Key Words

clinical research training; evidence-based practice; undergraduate research; associate degree program; respiratory care education; registered respiratory therapist

Introduction

Establishing the baccalaureate as the entry-level degree remains an important objective for respiratory care. The American Association for Respiratory Care (AARC) envisions the baccalaureate as the entry-level degree for registered respiratory therapists (RRTs) and has targeted 2020 as the date by which 80 percent of respiratory care practitioners should possess the degree or be working towards one.¹ RRTs with an entry-level baccalaureate degree (BD) in respiratory care, would have robust training in scientific research, evidence-based medicine and protocol-guided cardiopulmonary healthcare. While we strongly support attainment of an entry-level BD, most academic programs in respiratory care currently award the AD. A survey of respiratory care program directors revealed that scientific research, evidence-based medicine and clinical protocols were not taught in the majority of respiratory care AD programs.^{2,3} Much of the difficulty encountered by AD programs in providing their students with training in scientific research may be related to temporal and spatial limitations present in those programs when compared with BD programs. Since it may take several additional years for the BD to replace the AD as the most commonly awarded entry-level degree in respiratory care, we believe that sophomores in AD programs would benefit from exposure to a first, undergraduate clinical research experience that enables them to understand and apply fundamental research methods early in their respiratory care training. Such an undergraduate experience would be designed to operate in a temporally and spatially constrained AD curriculum and would include training in scientific research, evidence-based medicine as well as design and modification of clinical protocols; objectives that AARC has advanced as key to the success of professional RRTs who practice at the top of their license.

Transdisciplinary healthcare teams have become a critical part of the current learning healthcare system (LHS)³ and will likely play a pivotal role in assuring that the precision medicine initiative (PMI)⁴ achieves its stated goals of delivering the right protocolized care,⁵ to the right patient, at the right time. RRTs have become indispensable members of transdisciplinary healthcare teams⁶ which are known for using as well as producing scientific findings to improve the safety, therapeutic efficacy and cost-effectiveness of cardiopulmonary healthcare protocols. Originally referred to as multidisciplinary and later interdisciplinary teams, today's transdisciplinary teams⁶ are distinguished by their extensive use of collaborative, clinical role-release training⁷ which enables interprofessional sharing of knowledge and skills that expand the scope of practice

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for participating clinical disciplines and improve healthcare outcomes. Since transdisciplinary teams use findings from the best available scientific literature to design clinical protocols, professional, RRT clinician-scientists are needed who can critically evaluate scientific findings in order to modify established protocols and/or design them de novo. To engage in this type of advanced practice, RRTs will need to be conversant with current scientific literature, understand evidence-based medicine, and apply research knowledge and skills.

In a previous educational research project⁸ involving sophomores ($N = 6$) who were certified respiratory therapists (CRTs), we demonstrated that undergraduate clinical research consisting of non-invasive cardiac output (NICO) monitoring could be systematically undertaken by students, with advanced academic standing, in an AD program. The current project is an extension of that pilot study and was undertaken to determine whether traditional respiratory care students, without clinical credentials and without post-graduate clinical experience, could similarly employ NICO monitoring of mechanically ventilated patients with amyotrophic lateral sclerosis (ALS), as part of their first, undergraduate research experience. The current education research project did not constitute clinical research because it applied instrumentation and procedures in routine current clinical use at the clinical affiliate where the clinical practicum took place. Nevertheless, patient participants and their clinical caregivers received comprehensive explanations of the project and the former were aware that they could decline participation in the project at any time.

Methods

Undergraduate RC Research Based on Bioscience Model

Educational practice guidelines used in designing our undergraduate clinical research experience were adopted from *Vision and Change in Undergraduate Biology Education*.⁹ Our sophomores' research experience was closely modeled after research training provided in bioscience programs.¹⁰ Guidelines used to structure our research experience are shown in Table 1.

Table 1 Bioscience Guidelines for Research Experience

- 1) Help sophomores connect scientific concepts to real-world problems
- 2) Frame scientific problems in real-world clinical context
- 3) Exhibit passion that clinician-scientists feel for science
- 4) Exhibit delight in sharing scientific understanding with others
- 5) Engage sophomores as active colleagues in an iterative process of inquiry
- 6) Help sophomores experience the advances and limitations inherent in research

In spite of a smaller scope relative to graduate research training, undergraduate research programs often generate findings comparable to those produced by graduate-level programs. The US National Science Foundation (NSF) as well as numerous local agencies have been known to support community colleges wishing to develop innovative undergraduate scientific research programs. The importance of grant-supported undergraduate scientific research opportunities in helping the profession of respiratory care to grow and mature cannot be overstated.

Preparing for Clinical Research

Didactic Presentations

Prior to beginning their research experience, sophomores ($N = 16$) completed a proctored pre-test consisting of 20

multiple-choice research content questions (5 points per question) to evaluate baseline knowledge of selected, fundamental research concepts. Sophomores then received didactic instruction in fundamental research methodology consisting of introductory special topic sessions (Table 2) delivered during the first four weeks of a second-year advanced respiratory care course in the AD curriculum. Instruction in respiratory research methodology was based on content from articles in *Respiratory Care*¹¹⁻¹⁵ and clinical research findings¹⁶ produced at James A Haley Veterans' Administration Hospital (JAHVA), Spinal Cord Injury (SCI) Center, Tampa, FL, the clinical affiliate where the research practicum took place.

Table 2 Introductory special topic sessions

Topic 1 - Neurorespiratory care

- a. Neuroscience for respiratory therapists
- b. Introduction to neurorespiratory care
- c. Neurorespiratory care for patients with ALS

Topic 2 - Respiratory care research methods

- a. Randomized controlled trials & case series
- b. Diaphragmatic pacer – a case study
- c. Introduction to volumetric capnography

Topic 3 - Home health care

- a. Introduction to home health care
- b. Rural health care – an ALS research project

Topic 4 - Pulmonary function testing

- a. Overview of PFTs in clinical research

Laboratory Experiences

In our respiratory care laboratory at the college, students received a compact disk (CD)¹⁷ that provided interactive training on clinical use of the NM3 non-invasive cardiac output (NICO) monitor that they would be using for bedside acquisition of patient cardiopulmonary data. A pre-requisite for performing bedside measurements was attainment of a score $\geq 90\%$ which qualified sophomores to earn a certificate of completion from Philips Healthcare, Inc. manufacturer of the NICO monitor. Students received hands-on laboratory-based training with NM3 monitor.

Clinical Experiences

At bedside, a faculty clinical facilitator provided sophomores with a final procedural briefing, after which students applied the NM3 mechanical circuit to patients' Trilogy 202 (Philips Respironics, Murrysville, PA) ventilator circuit to measure cardiopulmonary parameters listed in Table 3.

Table 3 Measured Cardiopulmonary Parameters

- 1) Cardiac output (CO)
- 2) Pulse oximetry (SpO₂)
- 3) Alveolar minute volume (MV_{Alv})
- 4) Carbon dioxide elimination (VCO₂)
- 5) Dynamic chest compliance (C_{dyn})
- 6) Airway resistance (Raw)

Students recorded data from NM3 monitor, onto a structured data sheet.

Design of Clinical Research Practicum

Working in teams of two students, a clinical instructor and

faculty clinical facilitator, sophomores attended two, full, clinical research practicum days. Students were introduced to the chest optimization protocol (COP),¹⁶ an evidence-based protocol-guided multi-modal chest physiotherapeutic intervention (Table 4) implemented daily, by staff RRTs at the clinical affiliate.

Table 4 Components of chest optimization protocol (COP)

- 1) Body repositioning in supine or Trendelenburg position
- 2) Mechanical in/exsufflation-assisted sputum mobilization
- 3) Aerosolized bronchodilation
- 4) Pulmonary hyperinflation

COP was originally developed by JAHVA, SCI Center, Department of Neurorespiratory Care, to prevent/treat atelectasis, mucus plugging and pneumonia, all of which are pulmonary complications that represent significant barriers to weaning from mechanical ventilation and are associated with high rates of morbidity and mortality in cohorts with neurotrauma or neurodegeneration. NICO monitoring utilizes volumetric capnography to estimate cardiopulmonary parameters that may be used as surrogate indicators of cardiopulmonary function following a protocol-guided therapeutic intervention.

Research Practicum – Day 1

On day one of the 2-day practicum, bedside discussions with sophomores stressed application of clinical problem-focused research. By the end of day one, students were able to place patients in Fowler's and supine positions and administer evidence-based protocol-guided COP as listed in Table 3.

Research Practicum – Day 2

On day two of the 2-day practicum, sophomores performed measurements of cardiopulmonary variables pre- and post-chest optimization with patient first in Fowler's (pre-COP) position and then in supine (post-COP) position. Student teams eventually collected physiologic data from all mechanically ventilated patients with ALS in units SCI-B and SCI-FV. As a class, back at the college, sophomores later performed data analysis on the accumulated data set, using SPSS 24 (SPSS, Inc: Chicago, IL), software,¹⁸ to determine whether implementation of COP was associated with significant changes in any of the measured cardiopulmonary parameters.

Evaluation of Students' Skills

At the end of the 2-day research practicum, student teams presented their findings to the clinical instructor and faculty clinical facilitator who used a sophomore research skills inventory to evaluate gains in research skills according to five learning objectives listed in Table 5.

Table 5 Sophomore research skills inventory

- 1) Student explained rationale for research practicum
- 2) Student explained how the practicum facilitated learning of research methods
- 3) Student administered protocol to patients safely and efficaciously
- 4) Student measured data with NM3 monitor safely and efficaciously
- 5) Student recommended modifications to protocol based on best available evidence

Students who exceeded a given learning objective earned 20 points, those who met the learning objective earned 15 points

and those who did not meet a learning objective earned 5 points. Exceeding all five learning objectives earned a maximum of 100 points. Earning at least 85 points was deemed evidence that student had acquired fundamental research skills. Each skill had previously been conceptually aligned with didactic and laboratory-based learning activities.

Evaluation of Students' Knowledge

After completion of research practicum, the sophomore class completed a post-research practicum test, identical to pre-research practicum test taken earlier, to measure gains in research knowledge.

Data Collection and Analysis

Scores for sophomore participants were entered into a SPSS 24 data spreadsheet for repeated measures analysis of variance (RMANOVA) statistical modeling. Statistical significance was established at $P < .05$

Results

Comparative Analysis of Educational Outcomes

Mean age of sophomores ($N = 16$) was 37 years, majority (69%) were female ($N = 11$), and none had previous associate or higher level degree(s). Average difference of 23 points between pre- and post-research practicum test scores reflected significant ($p = 0.0001$) gains in research knowledge as shown in Table 6. Additionally, sophomores achieved high scores on the sophomore research skills inventory.

Discussion

Clinical Research in AD Programs

A first, undergraduate research experience should include opportunities that enable students to acquire fundamental research knowledge and research skills. Respiratory care educators generally agree that elements of clinical research should be introduced early in a respiratory care curriculum and these elements should be gradually expanded in subsequent courses to help students progressively understand the multifaceted role that scientific inquiry plays in helping practitioners engage in clinical research and apply research findings. Didactic discussions should be conceptually aligned with laboratory sessions and clinical practica to help students gain relevant research knowledge, skills and scientific dispositions. We have shown that an AD respiratory care program with temporal and spatial curricular constraints can nevertheless offer a first, clinical research experience that gives sophomores opportunities to apply fundamental research knowledge and research skills at the bedside. While the optimal duration of such an experience will need to await further study, our findings suggest that four days of didactic presentations plus one laboratory work session, plus two days of a hospital-based clinical research practicum appears to be a reasonable length of training for sophomores in an AD program.

A study of 348 programs in respiratory care revealed that research competencies are taught more often in BD programs than in AD programs.^{19,20} However, AD programs can often form partnerships with selected clinical affiliates, commercial vendors and community-based grant sources in order to offer experiences that help students achieve fundamental knowledge and skills in clinical research. The collaborative educational venture between our college, one of our clinical affiliates and a commercial vendor not only resulted in a unique, real-world clinical research experience for students, it also generated significant, student-

Table 6 Descriptive Statistics

	Mean	Std. Deviation	95% Confidence Interval		N
			Lower Bound	Upper Bound	
Pre-research practicum test score	52.81	12.11	46.36	59.26	16
Post-research practicum test score	75.94	11.86	69.62	82.26	16
Sophomore research skills inventory score	93.75	5.63	90.75	96.75	16

recommended changes to an established clinical protocol. Hence, findings from student-driven research enabled affiliate RRTs to re-evaluate established evidence-based clinical practice guidelines in light of students' findings. Parenthetically, student-driven clinical research may be an important, previously unappreciated resource for clinical institutions seeking periodic, independent, impartial checks of their clinical processes as a way to maintain efficacious evidence-based protocols capable of achieving desired patient care outcomes. A student-driven research process of this type might also be a previously untapped asset for clinical departments vying for the AARC's coveted Apex Recognition Award which is bestowed on institutions whose RRTs systematically translate their professional knowledge and skills into superior patient care.²¹

Students Input Improves Protocol

A composite of sophomores' protocol redesign recommendations is shown in Table 7.

Table 7 Sophomore's Recommendations for Redesigning COP

- 1) Undertake actual IRB-approved study of mechanically ventilated patients with ALS
- 2) Study the effect of more positional changes, in mechanically ventilated ALS cohort
- 3) Enable students to deliver small volume nebulizer (SVN) treatments as part of protocol
- 4) Enable students to deliver MI/E-assisted tracheal suctioning as part of protocol
- 5) Enable students to deliver protocol as used for spinal cord injury cohort
- 6) Simultaneously measure SCI and ALS cohorts with new NM3 NICO monitor

Students' recommendations suggests that they acquired fundamental research knowledge and skills during their undergraduate clinical research experience. Students opined that in the future, they should play a more direct role in placing patients in specific body positions and administering tracheal suctioning and aerosolized bronchodilators closer to time of physiologic measurements. Student's recommendations reveal a fundamental understanding of the role that continuing bedside clinical research plays in periodically modifying existing evidence-based clinical protocols in order to improve patient care.

Undergraduate Clinical Research Prepares Students for Advanced Patient Care

When an association was established between military service and ALS, Department of Veterans Affairs (VA) extended comprehensive clinical services to veterans with the disease.²²⁻²⁵ Since then, substantial numbers of veterans with ALS have opted for life support via mechanical ventilation. However, little is known about cardiopulmonary changes associated with long-term mechanical ventilation in the ALS cohort. This

need for knowledge was acknowledged when a *Resources for Excellence Grant*, from Hillsborough Community College (HCC) Foundation, was awarded to HCC, Department of Respiratory Care. The grant provided funding for: 1) an NM3 NICO monitor, 2) specialized NICO mechanical circuits and 3) SPSS 24 statistical software, which made it possible to undertake a hospital-based educational research project on behalf of veterans with ALS.

Establishing an undergraduate research experience in an associate degree program is conceptually supported by research in the life sciences which suggests that students who participate in undergraduate research are more likely to complete a bachelor's degree,²⁶ a previously stated objective of AARC. A first, undergraduate clinical research experience such as the one described herein may facilitate the academic path of respiratory care students from AD to BD programs by giving them a sampling of the type of academic work they will encounter in a BD program as well as the type of advanced clinical work they will be undertaking as professional RRT clinician-scientists. Additionally, undergraduate clinical research initiatives undertaken cooperatively by AD and BD programs can serve as a powerful demonstration that scientific research is present at every level of training in respiratory care programs; research that should be continued into clinical practice in order to continually improve patient cardiopulmonary care.

Increased knowledge and skills in research methodology are educational outcomes may enhance students' ability to focus on real-world clinical problems, engage in open-ended discussions, improve inquiry-oriented questioning and increase ability to engage in transdisciplinary collaboration.^{27,28} Findings from the current study suggest that a structured research experience in an AD program could play an important role in motivating sophomores to continue the process of acquiring critical thinking skills and clinical decision making capabilities that will enable them to practice at the top of their license as advanced respiratory care professionals.

Establishing a Research Network

Findings of the current study are in agreement with other studies indicating the need for expanding collaborative arrangements between AD programs and local clinical research affiliates. The next phase of our AD research experience is to offer a complete research methods course plus practicum, possibly as part of a BD educational consortium between HCC and St Petersburg College (SPC), a local, 4-year educational institution that offers the BD in respiratory care. There is also an unmet need in the local respiratory care community for research mentors and advisors who can assist fledgling research efforts in academic and clinical settings. The establishment of a formal, local clinical research network²⁹ could accelerate local and regional professional development of the respiratory care community by spurring scientific innovation, addressing in-service needs for research training, serving as a clearinghouse for evidence-based

protocol-guided health proposals and providing monitoring and oversight for community-based research initiatives in respiratory care. Nothing less would communicate the critical importance of on-going clinical respiratory care research to respiratory care students, clinical practitioners, patients, and other stakeholders.

Limitations of Study

A limitation of our study was the small sample size of student participants as well as the fact that the study was conducted at only one clinical affiliate. Nevertheless, this study was larger than a related pilot study (N = 6) conducted at the same clinical affiliate 5 years ago. Affiliations between AD and BD programs could lead to multi-center education research trial in the future. Another limitation was that although the educational experience was transdisciplinary in nature, only respiratory care sophomores participated. In the near future we anticipate inviting nursing, emergency medical technology, sonography and other allied health students at the college, to participate in the undergraduate clinical research experience. Inclusion of students from other disciplines will likely lead to improved team function, more comprehensive clinical protocols and better healthcare outcomes. Another important limitation was the lack of a standardized elapsed time from introductory special topic sessions to beginning of the 2-day research practicum for each research team of two sophomores. Some students began the research practicum within days after completing the introductory special topic sessions while others began the practicum more than 8 weeks after the sessions. We believe that transference of training from didactic and laboratory sessions to clinical research practicum at the clinical affiliate, while not identical for each student team, were nevertheless sufficient, given the constant application of research knowledge and skills throughout the advanced respiratory care course in which the research experience was embedded.

Conclusion

Sophomores participated in a first, clinical undergraduate research experience prior to graduating from an AD program in respiratory care. Participation in such an experience was associated with improved educational outcomes in fundamental research knowledge and research skills. Offering research experiences of this type may play an important role in helping sophomores' practice evidence-based medicine and implement protocol-guided cardiopulmonary healthcare. These experiences may also motivate students' to proceed from AD to BD programs where they can complete advanced training that will enable them to assume roles as professional RRTs.

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COPD and Chronic Respiratory Failure Management Revisited: Combining NIV with Activity for Improved Outcomes with the Life2000® Ventilation System (A case study follow-up)

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Introduction

Increased activity provides clinicians with an opportunity to improve COPD care. Physical activity is the single best predictor of survival in COPD patients, and for every 1000 daily steps increase at low to average intensity, COPD hospitalization risk decreases by 20%.^{1,2} While clinically beneficial, sustained activity is often difficult for COPD and pulmonary-compromised patients to achieve due to their high symptom burden. This is a follow-up to an original case study published in the Vol 12 No. 2 Spring 2017 edition of *Respiratory Therapy*.

Patient & Treatment Background

Peg is a fifty-nine-year-old, Caucasian female diagnosed with CRF consequent to COPD, with a history of hospitalizations and declining lung function dating back to 2011. In early 2014, she completed the pulmonary rehabilitation program at PeaceHealth United General Hospital in Sedro Wooley, WA. At that time, she was only able to walk 321 meters, while on 3 Lpm of oxygen, due to her SOB and high work of breathing.

By early 2016, despite her attempts to stay active, her FEV₁ had declined to 16% and her FVC declined to 36% of predicted. She was informed by her physician that she likely only had 3-4 months to live. She was placed on a nocturnal home ventilator and was directed to wear the device as much as possible, both at night and during the day. While the ventilator benefited Peg at night, the size and weight of the ventilator, mask, and circuit limited her ability to be active during the day, resulting in Peg having to spend much of her waking hours sedentary in a chair.

In the summer of 2016, Peg was placed on a Breathe ambulatory ventilator through the collaborative efforts of her home oxygen and respiratory equipment provider, Norco Medical, and her pulmonary rehab team at PeaceHealth Hospital.

The Breathe Life2000h ambulatory ventilator supplied to Peg is an FDA-cleared, one-pound, wearable, life-support ventilator. The Life2000h has no internal pressure generating source, which allows for the small footprint and weight. It is powered by an external pressure source, such as an oxygen cylinder or gas wall outlet in a medical facility. Breathe ventilators use the Venturi

effect to deliver a mixture of compressed gas (typically oxygen) and entrained room air through an unobtrusive nasal pillow interface, working to support patients that require mechanical ventilation. The small footprint of the Breathe ventilator and interface allows patients the opportunity to increase their mobility and ADL levels by providing a practical ventilatory solution that can reduce their symptom burden, whether at rest or while active. Studies have demonstrated that Breathe ventilators can reduce dyspnea and overall work of breathing while simultaneously increasing oxygenation and exercise endurance.³ A one-year retrospective study also resulted in a 79% mean reduction in healthcare utilization in a group of COPD patients placed on open ventilation therapy.⁴

The Life2000h allowed Peg to dramatically increase her daily functional activity level within her home. She was also able to engage in some light gardening and to take daily walks around her rural property. Over the course of ten months of Life2000h usage, Peg did not experience an exacerbation or hospitalization. She was also able to re-enroll in PeaceHealth United General Hospital's pulmonary rehabilitation program and use her ventilator during exercise. According to Kelly Shepard, her respiratory therapist instructor at PeaceHealth's rehabilitation program, "It is incredible to see a patient this fragile not experience an ER visit or admission, given that she was exacerbating several times per year. It is important for her quality of life as well as the healthcare system to see a meaningful way to reduce the risk of a readmission".

Follow-up Update

After approximately ten months of daily 16-18 hour therapy on the Life2000h Ventilator, Peg was doing well, but was utilizing a large number of oxygen cylinders on a weekly basis. As a result, Peg was transitioned over to Breathe Technologies' newly developed Life2000 Ventilation System in November of 2017. The Life2000 System is a modular ventilation system consisting of the one-pound Life2000 Ventilator (similar to the Life2000h) and the Life2000 Compressor. The portable Life2000 Compressor serves as the external pressure source needed to power the Life2000 Ventilator, and can work in tandem with a patient's home concentrator, thereby reducing their oxygen tank utilization while they are at home. The Life2000 System is FDA-cleared and has been assigned the PDAC billing codes required for billing by Medicare and commercial payers as a home ventilator.

The modular nature of the Life2000 System allows for three different configurations that can easily be adjusted to keep up

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with a patient's ventilatory needs throughout the day and night, as their activity levels change. By using the Extended Range configuration within her home, Peg was able to maintain her increased ADL levels, while dramatically reducing her weekly oxygen tank consumption, which was an operational and cost improvement for her home medical equipment provider, Norco Medical.

Outcomes Following Therapy Change

Approximately six months following Peg's transition over to the Life2000 Ventilation System, she was assessed during a home visit by therapy instructor Kelly Shepard from PeaceHealth's pulmonary rehabilitation program. Despite a documented FEV₁ of only 9%, Peg was able to ambulate over 2,000 ft (610 meters) on uneven ground, garden, navigate stairs, and walk uphill at a 40% grade with only moderate dyspnea. Peg's 610 meter walk distance represents over a 90% improvement in her walk distance when compared to her initial pulmonary rehabilitation walk of 321 meters on just oxygen alone.

After nearly two years of ambulatory ventilation therapy, Peg remains active daily, both in and outside of her home, in spite of her severely compromised lung function. In addition, to date, since starting on Breathe's open ventilation therapy, she has also not experienced a COPD-related exacerbation or hospitalization. When asked how Life2000 therapy has impacted her, Peg is quick to state, "This therapy has made all the difference in the world for me. The ability to remain active and independent has helped me both physically and mentally in better dealing with my COPD. I think this device has the right name, because to me this device IS life."

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Are We Giving Correct Instructions To Patients Performing Oscillatory Positive Expiratory Pressure Therapy?

The Role of a Slow Inspiration and Expiratory Flow Bias in Secretion Movement

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Introduction

It is common practice to give similar instructions to patients performing positive expiratory pressure (PEP) therapy and oscillatory positive expiratory pressure (OPEP) therapy. This is despite the fact that PEP and OPEP devices have different physical characteristics, which can affect mechanical outcomes such as flow and pressure. These instructions typically revolve around having the patient maintain an inspiratory to expiratory ratio of 1:3 or 1:4, which makes sense for PEP therapy but not necessarily for OPEP therapy. The purpose of this article is to provide a current look at instructions for use for PEP and OPEP devices and offer an alternative method for OPEP use based on the concept of expiratory flow bias.

Overview of Current PEP Instructions

A review of the literature found several published articles or textbooks which list instructions for use for PEP devices.¹⁻⁵ These usually contain three main components: 1) deeper breath than normal, but not all the way to total lung capacity (TLC) 2) active, but not forceful, exhalation to a pressure of 10 to 20 cmH₂O and 3) I:E ratio of 1:3 or 1:4. These instructions appropriately match the goal for PEP therapy, which is to increase functional residual capacity (FRC) thereby moving air behind secretions through collateral ventilation channels.

Overview of Current OPEP Instructions

OPEP tends to be performed similar to PEP with little delineation between the two. Some recommend adding an inspiratory hold while others say that exhalation should be with the help of abdominal muscles.^{6,7} The issue regarding I:E ratio is either not addressed or is recommended to be the same as PEP therapy. Therefore, instructions for use for OPEP devices may include: 1) deeper breath than normal but not all the way to TLC, 2) short breath hold, 3) active or forceful exhalation, but not all the way to residual volume, and 4) I:E ratio of 1:3 or 1:4. These instructions are sufficient to produce oscillation thereby helping to decrease viscoelastic properties of mucus, but are not optimal in order to drive mucus cephalad toward the oropharynx.

Concept of Flow Bias

Flow bias is the overall net movement of gas flow based on inspiratory and expiratory flowrates. As an analogy, two steps forward and one step back is overall net movement forward whereas two steps forward and three steps back is overall

net movement backwards. A higher peak inspiratory flow (PIF) than peak expiratory flow (PEF) generates overall flow movement toward the periphery of the lung. This is referred to as **inspiratory** flow bias. A higher PEF than PIF generates overall flow movement toward the mouth. This is referred to as **expiratory** flow bias.

Flow Bias in Secretion Clearance

In order to move secretions cephalad toward the oropharynx, researchers have shown there needs to be an expiratory flow bias. This means that PEF needs to exceed PIF by 17 l/m or by at least 10% (PEF/PIF ratio > 1.1).^{8,9,10} When inspiratory flow exceeds expiratory flow, the opposite will occur, that is mucus will move caudad toward the periphery of lung. The issue of flow bias and secretion clearance is specifically addressed in the following three studies.

In a bench study, Volpe et al conducted a crossover experiment in which twelve physiotherapists were asked to perform manual hyperinflation (MH) using a self-inflating resuscitation bag, a lung model, and simulated secretions.¹¹ The goal was to determine which method of MH, usual practice or recommended practice, resulted in the greatest movement of secretions outward. The study found that when the physiotherapists performed MH according to their usual practice a mean **inspiratory** flow bias of 55 l/m was created, moving secretions toward the test lung. In an actual patient situation this would drive secretions further down the lung instead of moving them cephalad toward the oropharynx. When they performed MH with a very slow insufflation and rapid release of the bag (recommended practice), a mean **expiratory** flow bias of 27 l/m was created, moving secretions away from the test lung. In clinical practice this would move secretions cephalad toward the oropharynx. The study's conclusion was that in order to remove secretions, MH should be performed with a slow inspiration so as to cause the greatest possible expiratory flow bias.

In another recently released article by the same group of authors, expiratory flow bias was studied in the context of mechanical insufflation-exsufflation (MI-E).¹² The study examined the effects of fast vs. slow insufflation on secretion displacement in three different lung model scenarios. They found that when the MI-E maneuver was applied with a slow insufflation, there was greater outward mucus displacement when compared to a fast insufflation. This was due to lower inspiratory flowrates and a higher expiratory flow bias when the MI-E device was set for slow insufflation.

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Finally, Li Bassi et al conducted an animal study with eight healthy pigs.¹³ The animals were intubated and ventilated while mucus velocity was fluoroscopically tracked using radiopaque markers. Inspiratory and expiratory flowrates were monitored as inspiratory time was prolonged. Six different I:E ratios were used: 1:2.9, 1:2, 1:1.4, 1:1, 1.5:1, and 3:1. The study found that expiratory flow bias and cephalad mucus movement improved as inspiratory time was prolonged. This was due to the reduction in inspiratory flow as the inspiratory time was increased.

Applying Expiratory Flow Bias to OPEP Therapy

Although instructions for use vary among OPEP devices — manufacturers, practitioners, and educators alike tend to recommend that exhalation last between three and four times longer than inspiration (I:E ratio of 1:3 or 1:4). However, this specific instruction when applied to OPEP therapy favors an inspiratory flow bias rather than an expiratory flow bias.

Consider the following example of an adult patient with a predicted inspiratory capacity of 3.0 liters. He is performing OPEP therapy at a respiratory rate of 15 breaths per minute and a deeper than normal tidal volume of 1500 ml. If the patient is to maintain an I:E ratio of 1:3, inspiration would be one second and expiration would be three seconds. In this situation, the inspiratory flowrate would be 90 l/m. If the patient is then instructed to exhale “actively but not forcefully”, it is unlikely they will be able to generate the expiratory flow necessary to produce an expiratory flow bias.

Now consider the same patient breathing at a slower respiratory rate of 10 breaths per minute and an I:E ratio of 1:1 (3 second inspiration and 3 second expiration). Assuming the same tidal volume of 1500 ml, the patient’s inspiratory flowrate would be 30 l/m. In this situation there is a greater chance of creating an expiratory flow bias since the inspiratory flowrate is lower.

To clinically illustrate these examples, a retrospective analysis of 42 healthy volunteers performing OPEP therapy found that only one subject consistently achieved an expiratory flow bias.¹⁴ This was due to the average inspiratory time among subjects being fairly short at 2.02 seconds, which tended to produce higher inspiratory flowrates. In fact, the mean maximum PIF in the study was 99 l/m \pm 29.9 while the mean maximum PEF was 54 l/m \pm 13.6, producing a mean PEF/PIF ratio of 0.55. In clinical practice, these metrics would produce a 45 l/m inspiratory flow bias driving secretions further down the lung. Clearly had the average inspiratory time been longer and inspiratory flow lower — the mean PEF/PIF ratio would have been higher and a greater number of subjects would have achieved an expiratory flow bias. It is worth mentioning that all of the subjects received the same exact pre-instructions highlighting the subjectivity of the phrase, “take in a slow, deeper than normal breath.”

Alternative Method: Coach the Patient to Slow Down Inspiration

Coaching patients to slow down inspiration is imperative in order to optimize secretion clearance during OPEP therapy. Simply giving pre-instructions will not result in maximum efficacy. Constant teaching and feedback is necessary during the session. Instead of worrying about maintaining a specific I:E ratio, a more rational approach would be to first have the patient slow down their respiratory rate as much as possible during the OPEP session. This will allow for a greater cycle time so that the patient can perform three critical elements: 1) inhale as slow as possible,

2) perform a short breath hold, and 3) exhale forcefully through the device. These elements are crucial in order to generate an expiratory flow bias, increase distribution of ventilation, and create adequate oscillatory flow amplitude. Again, continuous coaching during the session is the key to efficient therapy.

Conclusion

Instructing the patient to maintain an I:E ratio of 1:3 or 1:4 during OPEP therapy is not conducive to producing an expiratory flow bias. An inspiratory to expiratory ratio of 1:1 or even slightly inverse is not out of the question and is actually more in line with creating the PEF/PIF ratio necessary to move mucus cephalad toward the oropharynx. Furthermore, we need to move away from thinking about OPEP devices in terms of pressure and instead think about them in terms of flow. Expiratory flow bias will be maximized when the respiratory care practitioner sets the OPEP device on the lowest resistance and instructs the patient to take the slowest inspiration possible.

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Over Seven Years of Experience with an Automated Subglottic Aspiration System in a Comatose Patient with Traumatic Brain Injury

Katja Fain, SLP, and Sarah Lindacher, SLP, MSc

Abstract

Beginning in January 2010, a comatose traumatic brain injury patient with severe neurogenic dysphagia was the first patient treated with an Automated Subglottic Aspiration System (ASAS). The system was designed to aspirate saliva and oropharynx secretions from above the ballooned cuff of a permanently blocked tracheal cannula. Since the patient's initial injury from a severe fall in 2006, the goal was to reduce the large amounts of saliva and secretions leaking out of the tracheostoma, which previously had been collected with materials such as towels and compress sponges, by using manual suction with syringes, and by using conventional suction pumps. Prior to using the new system, the patient's clothing, linens, and dressings had to be changed and other tracheostomy care procedures had to be repeated multiple times per day. The massive amount of paratracheal leakage was a major obstacle to treatment for improving the swallowing reflex, and put the patient at risk of developing aspiration pneumonia, which can result from secretions leaking into the lungs. For the first time, the ASAS made automated aspiration possible 24/7, and combined the capabilities to variably and precisely control suction pressure, duration, and frequency. The aspiration device was attached to the subglottic port of a tracheal cannula via a suction tube. After a few weeks of use, approximately 300ml of saliva and secretions were collected daily as compared to approximately 25ml with the use of the syringe. Nursing time was reduced to average levels, and the consumption of dressings and other tracheostomy supplies was greatly reduced. The patient's vital signs and swallowing reflex further improved under the clean and dry conditions. The comatose patient was able to comfortably tolerate continuous use of the ASAS for a total of 7.5 years (90 months), until the time of his death. The experience gained in this case has important positive implications for improving patient quality of life, for preventing aspiration pneumonia and potential cross contaminations, for improving staff conditions and quality of care, and for reducing the use of materials and other resources, and their staggering costs.

Introduction

In the case highlighted here, the patient, Mr Brunner (name changed), suffered a traumatic brain injury (TBI), after a severe stair fall in 2006. In the acute care hospital he was tracheostomized, to address a long and continuing need for mechanical ventilation. He showed no reaction to external stimuli, and only facial tactile stimuli could occasionally raise

the tone and grimaces. Communication attempts by Mr Brunner were not observed.

Upon admission to our long-term rehabilitation unit in Nuremberg, the patient remained comatose, but was no longer in need of continuous ventilation. His condition did not permit decannulation, however, because of severe dysphagia with massive salivation and secretions. From time to time, between stable respiratory phases, he exhibited respiratory insufficiency and periodically required additional mechanical ventilation.

After a few months of logopedic therapy, swallowing reactions were barely stimulated during the clinical swallowing examination. The swallowing frequency was greatly impaired and swallowing quality was ineffective. Protective reactions such as coughing were reflexive, delayed, impaired and ineffective. The lack of clearance features and massive paratracheal sputum leakage indicated a severe disturbance of sensitivity in the pharynx and laryngeal areas.

For much of the next four years, suctioning was conducted manually using syringes or other available suction devices. The introduction of tracheal tubes with subglottic suction ports for suctioning above the cuff offered promise, but techniques and suction pressures varied among caregivers, resulting in suboptimal aspiration and potential mucous membrane tissue irritation. The moist environment in the area of the stoma continued to be the cause of severe skin lesions. The clothing and even the bedding of the patient were always wet to moist, and quickly developed a foul odor and potential for cross contamination (See Figures 1-3). Endotracheal aspiration had to be conducted as many as 17-20 times per day. In January 2010, treatment with the Automated Subglottic Aspiration System (ASAS) was initiated (See Figure 4).

“[Prior to use of the ASAS] The clothing and even the bedding of the patient were always wet to moist, and quickly developed a foul odor and potential for cross contamination.”

The aspiration system was attached to the tracheal cannula via a subglottic port, every day for 24 hours, to aspirate above the cuff intermittently, around the clock. The system allowed for control of suction pressure, frequency, and interval. Various combinations of parameter settings were tried, as well as

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various tracheostomy tubes. Among the various tubes trialed, the Portex BlueLine Ultra Suctionaid (Size 8) was considered the best fit for the patient. The system developer, Helmut Fendler of Gesundheits Manager GmbH, Nuremberg, Germany, closely monitored the secretion volumes collected.¹ When relatively low ASAS negative pressures were applied, initial volumes collected were low, approximately 15 ml/day, and the stoma remained moist and extremely red.

“[Prior to the use of the ASAS] endotracheal aspiration initially had to be conducted as many as 17-20 times per day.”

A breakthrough in Mr Brunner’s case resulted with an ASAS pressure setting of -200 mbar (-150 mmHg), suction time of 18 seconds, and suction interval of 5 minutes (See Figure 5). After 4 days the collection canister accumulated 1000ml of secretions and the stoma was dry because there was no more overflow of secretions. After 6 additional days and an additional 1900 ml of secretions had been aspirated, the skin condition in the stoma area further improved (See Figure 6). Two years after the first use of the ASAS, daily secretions collected stabilized at almost 60 ml per day, and Mr Brunner’s stoma remained dry and clean (See Figures 7-8). By the time of his death in June 2017, he had been maintained successfully on the aspiration system for 7.5 years (90 months).

“After a few weeks of initial use and fine tuning [of the aspiration system], approximately 300ml of saliva and secretions were collected daily.”

The reduction in the volume of sputum and secretions collected, from 300ml daily initially, to 60ml daily after two years, were in part attributed to steady improvements in oropharyngeal sensitivity, which allowed the secretions to be recognized and swallowed. The 24/7 aspiration and gentle stimuli provided by the ASAS, were thought to have contributed to the gradual improvements in the swallowing reflex.



Figure 1. Intensive tracheostoma care required due to excessive secretion production and paratracheal leakage prior to use of ASAS.



Figure 2. Leaking paratracheal secretions before introduction of the ASAS.



Figure 3. Syringe (20 ml) used to aspirate secretions from subglottic port of tracheal tube.



Figure 4. Simex Automated Subglottic Aspiration System (ASAS) at bedside.

Discussion

In caring for patients with traumatic brain injury (TBI), the goals of the therapeutic team are to wean the patient from mechanical ventilation, to prevent life-threatening infections, to restore pharyngeal sensitivity and the swallowing reflex, and to help the patient, where possible, regain the ability to speak following decannulation. Equally important, as in the case of Mr Brunner, the automated subglottic aspiration system greatly improved his comfort and quality of life, as well as many other aspects of his



Figure 5. ASAS settings at -200 mbar, aspiration time 18 seconds, aspiration interval 5 minutes.



Figure 6. 900ml of sputum aspirated after 3 days.



Figure 7. Tracheostoma care with trach slit dressing used with automated subglottic aspiration system.



Figure 8. Dry tracheostoma after use of ASAS system.

care and care setting, despite the patient's comatose condition for the entire period of 7.5 years he was supported by the aspiration system.

The patient only required mechanical ventilation from time to time while in our long-term care facility. There were no differences between ventilated and non-ventilated periods with regard to the efficiency of the ASAS, the parameter settings or the aspirated secretion volumes.

Despite his limited need for mechanical ventilation while in our facility, Mr Brunner's case has far-reaching positive implications for mechanically ventilated patients and others requiring temporary or permanent use of a blocked cannula. Among this patient population, ventilator-associated pneumonia (VAP), and ventilator-associated events (VAE), remain leading causes of death and readmissions to intensive care units, and contribute to antibiotic resistance.² This case represented the first use of the ASAS in a long-term care setting. Additional experience with the ASAS in a long-term care setting was gained in the US, beginning in 2015.³⁻⁵ In 2016, Wolf reported extensive experience with the ASAS in an ICU facility in Hamburg, Germany.⁶

Gradual increases in the frequency of deblocking of the trachea are required to improve the swallowing reflex and improve clearance functions,⁷⁻⁸ but increases in deblocking times are associated with high risk. If infected secretions descend into the lower respiratory tract, they result in increases in bronchopneumonia rates.⁹⁻¹¹

Now known commercially as the Simex Automated Subglottic Aspiration System (ASAS), the system is programmable to address both the volume and viscosity of secretions. Negative pressure settings range from -60 to -300 mbar (-45 to -225 mmHg), with intervals ranging from 10-60 seconds (ON), and from 3-60 minutes (PAUSE). The aspiration system operates both quietly and gently. The system helps prevent the tracheal tissue damage associated with manual suctioning via syringe. Depending on syringe size and volume, a syringe puts -578 to -722 mmHg of force on the airway.¹² AARC guidelines recommend the use of negative pressures from -80 to -150mmHg.¹³

Over the course of Mr Brunner's treatment, experience with the system was gained and adjustments were made, based on changes in medication, tracheal cannula management, dysphagia-related functional improvements or dysfunctions, and potential infections. All these factors influenced the amount and nature of the aspirate. In addition to the removal of secretions, it was observed that use of the ASAS system had a positive effect on the swallowing frequency as well as the swallowing effectiveness, made apparent by the reduction of secretions collected to 60ml per day, from the original 300ml per day.

“Savings associated with use of the ASAS device, in this case alone, amounted to...€392,692.50...over the entire 7.5 years.”

Despite initial skepticism, all of the health professionals involved in the care of Mr Brunner—nurses, speech therapists, and physicians, were “amazed” at the amount of secretions/sputum removed. From the start of logopedic therapy to improve the

swallowing reflex, use of the system permitted deblocking of the trachea once an hour, versus zero times per hour previously.

The frequency of stoma care, and the amount of consumables used dropped dramatically with the use of the ASAS aspiration system. The need for tracheostoma care dropped from 14 times a day, to 2-3 times daily. The need for endotracheal aspiration dropped from 17-20 times a day, to 5-7 times daily. The time saved allowed staff members to focus on other important patient-related activities.

The reduced need and frequency of care procedures had a tremendous impact on the need for consumables. The results are quantified and presented in Figure 9. Savings associated with use of the ASAS device, in this case alone, amounted to €1,007.00 for one week; which extrapolates to €52,359.00 for one year; and €392,692.50 in savings over the entire 7.5 years (See Figure 10). Device-related costs were €1,314 per year (or total of €9,857 during 7.5 years), generating over €50,000 in annual net savings.

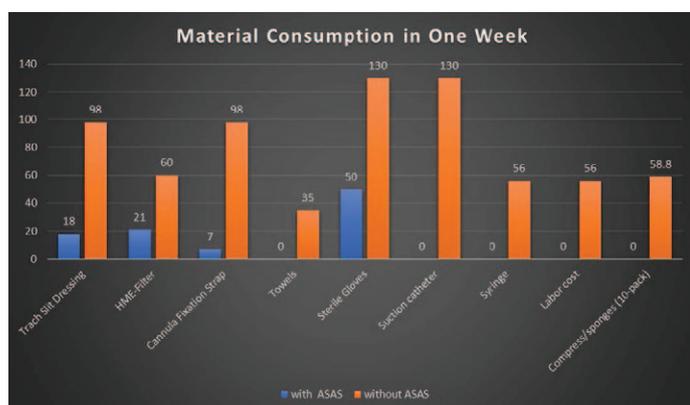


Figure 9. Weekly material savings after utilization of ASAS.

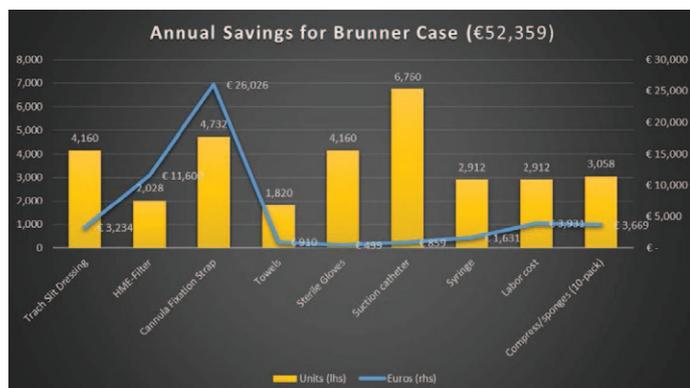


Figure 10. Device related savings were €52,359 per year. Device-related costs were €1,314 per year, generating over €50,000 in annual net savings.

Conclusion

The long-term case of coma patient, Mr Brunner, illustrates the many benefits associated with the use of an Automated Subglottic Aspiration System (ASAS). Following treatment, the patient's quality of life improved greatly. His stoma was kept clean and dry, he was made comfortable, and had healthy skin, without odor and stigma. In combination with comprehensive, high quality care, he was protected from infection and from contaminating others. Use of the system in this individual patient over 7.5 years dramatically reduced the quantity of consumables used in his care, improved the clinical environment, saved

countless numbers of staff hours, and saved hundreds of thousands of Euros.

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Respiratory Compromise: First, Do No Harm

Greg Spratt, BS RRT CPFT

Postoperative Respiratory Compromise

Primum non nocere is a Latin phrase attributed to Hippocrates, author of the physician's oath, translating to the oft heard reminder "first, do no harm." This is often not the case in today's healthcare system with estimates of between 210,000-400,000 deaths each year are associated with preventable harm in hospitals. Serious harm or injury is estimated to be 10- to 20-fold more common than deaths.¹

A HealthGrades report states that 1 in 10 monitored adverse events was due to postoperative respiratory failure. The incidence rate is 17.18 per 1,000 patients, a rate higher than sepsis and more than triple the cost. The cost per respiratory failure event was estimated at \$53,500. HealthGrades mortality data also includes 'death among surgical inpatients with serious treatable complications' (previously known as 'failure to rescue') and 'post-operative pulmonary embolism or deep vein thrombosis'. These categories, along with postoperative respiratory failure, ranked first (death), third (respiratory failure), and fifth (pulmonary embolism) in rate of adverse events, and accounted for 60% (47,759 of 79,670) of reported deaths in this population. HealthGrades data only included Medicare patients, which therefore under-represents the total impact of these events to the system and patients.²

Respiratory compromise (RC), defined as respiratory decompensation through insufficiency, failure and/or arrest (Figure 1), may be preventable through earlier identification and intervention.^{3,4,5} Respiratory conditions are the leading cause of ICU admissions,⁶ rescue calls,⁷ and 'code blues',⁸ and occur in nearly 1 of 8 elective surgery patients and 1 in 14 of all Medicare patients.^{9,10} It is projected that RC costs will reach \$37 billion annually by 2019,⁸ and it ranks among the AHRQ *Top 5 Most Rapidly Increasing Hospital Costs*.¹¹ Patients that develop RC while on the general care floor (GCF) have a mortality rate 29 times that of GCF patients that do not develop RC.¹² In light of these sobering statistics, the potential for prevention offers a ray of hope. In a review of primary respiratory arrests, 64% were classified as potentially avoidable, and, of these, all had inadequate treatment prior to the event, while 67% demonstrated clinicians failed to respond to abnormal findings.¹³ (Figure)

Several organizations, including The Joint Commission,¹⁴ the Anesthesia Patient Safety Foundation (APSF),^{15,16} the Society for

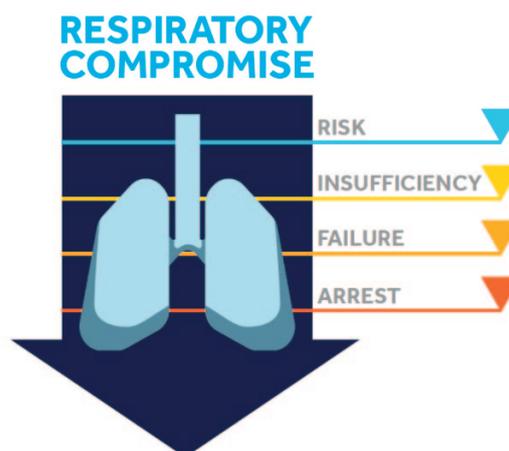


Figure 1. Respiratory Compromise Cascade

Hospital Medicine,¹⁷ and the Association for the Advancement of Medical Instrumentation,¹⁸ have focused efforts on the problem of RC in post-operative patients secondary to opioid-induced respiratory depression (OIRD), but preventable RC can occur in patients across the hospital and the healthcare continuum via a variety of etiologies.³ Opportunities for improving outcomes exist in many patient populations.

Role of Continuous, Electronic Monitoring

Currently, the most common method of monitoring patients on the postoperative GCF is intermittent vital signs (eg, every 4-6 hours¹⁹), which the organizational recommendations referenced below state to be clearly inadequate. Nurses and other clinicians often face tremendous challenges in monitoring multiple patients simultaneously on the GCF. A study of medical-surgical nurses in 36 hospitals showed that, on average, they spend only 7% of their time on patient assessment and reading vital signs.²⁰ Manual vital sign monitoring is labor intensive and leaves patients unmonitored for 96% of the time.²¹ Spot-check entries may be inaccurate and not represent the patient's true condition.^{19,22} Sun demonstrated that intermittent SpO₂ spot checks missed 90% of hypoxemic episodes (recorded by blinded continuous oximetry) in which patients desaturated to less than 90% for at least one hour. He also points out that the patient with desaturations during sleep, may be awake/awakened and even instructed to take deep breaths when SpO₂ is low until a satisfactory vital sign is recorded, providing a false sense of normality.¹⁹

A review of opioid-related deaths and injuries resulting in litigation found that 97% of postoperative opioid-induced

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Common ⁶⁻¹⁰	Costly ^{8,11}	Deadly ¹²	Preventable ¹³
<ul style="list-style-type: none"> • Leading cause of ICU admissions, rescue calls, and 'codes' • 1 of 8 elective surgery patients • 1 in 14 of all Medicare patients 	<ul style="list-style-type: none"> • RC costs will reach \$37 billion annually by 2019 • AHRQ <i>Top 5 Most Rapidly Increasing Hospital Costs</i> 	<ul style="list-style-type: none"> • Mortality rate 29 times that of GCF patients that do not develop RC 	<ul style="list-style-type: none"> • Nearly 2 of every 3 cases of respiratory arrest found to be potentially avoidable

Figure 2. Respiratory Compromise – Common, Costly, Deadly, and Preventable.

respiratory depression events (OIRDEs) on the ward were deemed preventable with better monitoring and response. Forty-two percent of OIRDEs in this analysis occurred within 2 hours of the last nursing check and 16% within 15 minutes.²³

The organizations mentioned above, and several others, have recommended the use of continuous, electronic monitoring of oxygenation and ventilation to enable early identification [Figure 3]. Several methods of monitoring are available, including pulse oximetry for oxygenation, capnography, RR, and tidal volume for quality of ventilation, each with its own inherent benefits and limitations. Though a detailed comparison is beyond the scope of this paper, ideally, the monitoring should be continuous and non-invasive, with high reliability, sensitivity (ie, no false negatives), specificity (ie, minimal false/non-actionable alarms), and a fast response time to enable early clinician intervention as injury/death can ensue within minutes when events occur. An independent comparison of characteristics from several potential monitoring parameters is provided in Table 1.

Table 1. Common Methods of Monitoring Respiratory Compromise (re-printed with permission from Anesthesia Patient Safety Foundation from APSF)¹⁵

Table 1. Comparison of Available Monitoring Modalities for Detection of Opioid-Induced Respiratory Depression in the Postoperative Period				
Monitoring Modality	Sensitivity *	Specificity	Reliability	Response Time
P _a CO ₂ (intubated)	High	High	High	Fast
S _p O ₂ (no O ₂ supplement)	High	Moderate-High	High	Fast
P _a CO ₂ (unintubated)	High	Moderate-High [§]	Moderate	Fast
P _r CO ₂	High	High	High	Slow
P _i CO ₂	High	Moderate	High	Slow
P _e CO ₂	Moderate	High	Low-Moderate [‡]	Medium
S _p O ₂ (with O ₂ supplement)	Moderate	Moderate	High	Slow
Clinical assessment (skilled clinician)	Moderate	Moderate-High	Moderate	Slow
Respiratory rate (newer technology)	Moderate	Moderate [†]	Moderate	Medium
Tidal volume (unintubated)	Moderate	Moderate	Low	Medium
Chest wall impedance (for respir. rate)	Low-Moderate	Low [†]	Low	Medium
Clinical assessment (less skilled clinician)	Low-Moderate	Low-Moderate	Low-Moderate	Slow

* Definitions: Sensitivity = positive in the presence of respiratory depression (low false negative rate); Specificity = negative in the absence of respiratory depression (low false positive rate); Reliability = accuracy and availability (likelihood of an available and accurate reading at the time of respiratory depression); Response time = average time from the onset of respiratory depression until the variable reads abnormally if it is going to do so.

§ If P_aCO₂ is high, this is highly specific for respiratory depression. However, if is low, because of unknown dead space, it can only be used as a measure of respiratory rate.

‡ New P_eCO₂ technologies may be more reliable.

† In some patients, respiratory rate alone may not be a good measure of opioid-induced respiratory depression.

There are several inherent challenges with broad implementation of continuous monitoring of all postoperative patients on the general care floor, known as 'surveillance monitoring'. These include, but are not limited to:

- Cost of the monitors and associated consumables/sensors for every bed/patient
- Unnecessary disruption to workflow due to false alarms, which are often the result of setting alarm thresholds too close to patient baseline; failure to customize the alarm settings to individual patient conditions; technical errors in application

of sensors; and removal of sensors by patients (eg, non-compliance or removal to ambulate)²⁶

- Challenges in education of hospital personnel on interpreting monitoring parameters, waveforms, and trends, especially parameters less familiar to the primary bedside clinicians (eg, GCF nursing)

These challenges have led some hospitals to monitor only those patients deemed to be at higher risk based on a protocol or algorithmic assessment of risk factors, known as 'conditional' or 'risk monitoring'.²⁷ Some have suggested that risk cannot be adequately assessed at present and that monitoring only higher risk patients leaves unmonitored patients at risk; thus, surveillance monitoring of the entire population is preferred.¹⁵

Mechanisms and Risk Factors for Postoperative Respiratory Depression

A multitude of respiratory physiologic mechanisms are significantly compromised during and following anesthesia and exacerbated with administration of opioids and other respiratory depressant medications (eg, benzodiazepines, sleep aids, antihistamines, etc.) used frequently across the hospital. Detailed explanations are covered by other work and will not be repeated here but include depression of central respiratory drive resulting in alveolar hypoventilation, diminished compensatory responses to hypoxia and hypercarbia, respiratory/airway muscle tone

Case Study – Leah's Story

After successful surgery to repair pectus carinatum, Leah, age 11, complained of considerable pain and fentanyl was repeatedly increased along with giving Ativan for "anxiety." Despite increasing dosages of opioids and addition of a benzodiazepine, Leah was not continuously monitored. After midnight, her mother, Lenore, exhausted, fell asleep next to Leah in bed. About 2 hours later, Lenore awoke and found her daughter Leah had died.



"Would real-time monitoring have saved Leah? That is one of the many questions that I have asked myself every day since I found my daughter, Leah, dead in her hospital bed. The answer is yes, it would have." — Lenore Alexander

Physician-Patient Alliance for Health & Safety Website: <http://www.ppahs.org/2012/02/guest-post-yes-real-time-monitoring-would-have-saved-leah-2/>

Additional patient stories can be viewed at <http://www.respiratorycompromise.org/patient-stories/> and <https://patientsafetymovement.org/advocacy/patients-and-families/patient-stories/>. — Lenore Alexander (Mother of Leah)⁰¹

Table 2. Risk Factors for Postoperative Pulmonary Complications

Reference	PRODIGY: Seeking Answers ³¹	The Joint Commission Sentinel Event Alert #49 ¹⁴	Society for Hospital Medicine RADEO Guide ¹⁷
Risk Factors	<ul style="list-style-type: none"> • Sleep disordered breathing • Obesity • Advanced age • Post-surgical status • Increased opioid dose requirement, concomitant use of other sedating medications • Comorbidities including pulmonary or cardiac disease • Opioid use via patient-controlled analgesia systems • Smoking 	<ul style="list-style-type: none"> • Sleep apnea or sleep disorder diagnosis • Morbid obesity with high risk of sleep apnea • Snoring • Older age • No recent opioid use • Post-surgery, particularly if upper abdominal or thoracic surgery • Increased opioid dose requirement or opioid habituation • Longer length of time receiving general anesthesia during surgery • Receiving other sedating drugs, such as benzodiazepines, antihistamines, diphenhydramine, sedatives, or other central nervous system depressants • Pre-existing pulmonary or cardiac disease or dysfunction or major organ failure • Thoracic or other surgical incisions that may impair breathing • Smoker 	<ul style="list-style-type: none"> • Age >55 years • Obesity (BMI >30) • Untreated OSA • Snoring or witnessed apneas • Excessive daytime sleepiness • Retrognathia • Neck circumference >17.5" • Pulmonary/cardiac disease • Kidney/liver failure • Diminished functional status • Smoker • ASA Classification >3 • Increased opioid dose requirement • First 24 hrs of opioid use • Pain controlled after period of poor control • Prolonged surgery (>2 hrs) • Incisions which impede ventilation • Concomitant use of sedating agents • Large, single bolus opioid administration • Continuous opioid infusion in opioid-naïve • Naloxone administration

reduction precipitating anatomic airway obstruction, diminished functional residual capacity, ventilation/perfusion mismatching, pulmonary shunt, diffusion impairment, increased oxygen extraction, diaphragmatic displacement, and pulmonary atelectasis.^{24,29}

In the postoperative period, response to hypoxia and hypercarbia can remain blunted secondary to residual effect of anesthesia and the use of opioids for acute pain which is exacerbated when used in combination with other potential respiratory depressants. Atelectasis development may continue postoperatively secondary to low tidal volumes due to pain, especially during abdominal and thoracic surgery, which also makes clearing secretions from the airway difficult due to impaired cough. Functional residual capacity reaches a low point 1 to 2 days postoperatively and lung function may be diminished for days or even weeks postoperatively.^{28,29}

Factors which may increase the risk of postoperative pulmonary complications have been referenced in several works on the topic and a few are summarized in Table 2 below. Risk factors can be classified in 3 groupings: 1) patient factors (ie, conditions inherent to the patient, such as comorbidities, occult conditions

such as undiagnosed or untreated OSA, obesity, age, etc.), 2) treatment factors (ie, iatrogenic interventions provided to the patient, such as medications given, procedures performed, etc.), and 3) area of care factors (ie, patient to nurse ratios, type/quality of monitoring, protocols in practice, knowledge of clinicians in responding to precursors to events, etc.). It is often an interaction of several factors which creates the ‘perfect storm’ scenario leading to catastrophic injuries and deaths [Figure 4]. Furthermore, literature notes that the prevalence of certain patient factors, such as obesity, has dramatically increased in the US population, which may make this scenario more frequent.³⁰

Risk Assessment

Despite these known risk factors, because of the complexity and interactions of factors involved, reliable prediction of postoperative RC remains elusive. No standardized, validated tool to predict risk is available for determining which patients are at highest risk. In addition to the nearly ubiquitous use of opioids in postoperative patients, half of non-surgical (ie, medical GCF) patients receive opioids and there is little or no data available in the literature which can characterize the magnitude or risk factors of RC secondary to opioids in this population.³²

There is a glaring need for a simple risk prediction tool to stratify risk of OIRD while on the GCF which has been emphasized in previous work on this issue.³¹ Such a tool could serve to guide which patients would benefit most from continuous monitoring (ie, ‘risk monitoring’) when implementation challenges prevent surveillance monitoring of all patients. Ideally, it should be automated and ongoing as manual calculations based upon so many risk factors would be difficult, time consuming, and fail to reflect changes in treatment or the patient’s condition.

As the APSF suggests, such an approach might serve as an interim step toward a more ideal solution of surveillance monitoring all patients. Certainly, selective risk monitoring is preferred to current paradigms of intermittent vital sign monitoring and may help to demonstrate that improved patient

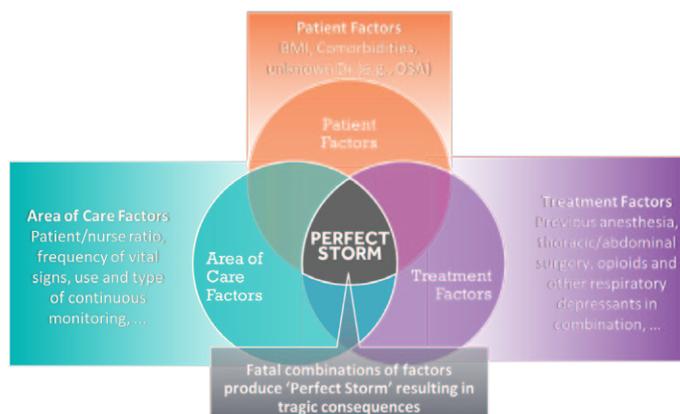


Figure 4. Types of Risk Factors

Figure 3. Organizational Recommendations for Continuous Monitoring of Oxygenation and Ventilation

Organization	Recommendations
The Joint Commission ¹⁴	Sentinel Event Alert #49 – Safe use of opioids in hospitals: Develop policy for ongoing monitoring (eg, adequacy of respiration and depth of sedation) of patients receiving opioids. Capnography may be used to monitor ventilation. Educate not to rely on oximetry alone, especially with supplemental oxygen use, where capnography shows value to monitor adequacy of ventilation.
Anesthesia Patient Safety Foundation ^{15,16}	Postoperative Monitoring with Opioid Use: Monitor of oxygenation and ventilation should be considered for all patients receiving opioids to reduce respiratory depression. Monitor the adequacy of ventilation (eg, capnography) when supplemental oxygen is used.
Society for Hospital Medicine ¹⁷	Reducing Adverse Drug Events Related to Opioids (RADEO) Implementation Guide Opioid-induced respiratory depression is noted by respiratory rate < 8 to 10 breaths/min, desaturations, or high etCO ₂ . Based on risk, selective use of capnography for inpatients receiving opioids may prevent opioid-related respiratory failure. Continuous electronic monitoring of ventilation may allow for early identification and enable prevention of opioid-induced respiratory depression. Pulse oximetry alone can be a late detector of respiratory depression when using supplemental oxygen may delay desaturation in the presence of RD.
Association for the Advancement of Medical Instrumentation ¹⁸	National Coalition to Promote Continuous Monitoring of Patients on Opioids – Supplement ongoing assessment of sedation and respiratory status with continuous electronic monitoring in patients receiving opioids for early identification of respiratory compromise. Experience demonstrates a protocol including continuous respiratory monitoring increases the quality of care in a financially sustainable manner.
American Society of Anesthesiologists ²⁴	Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration – Monitor oxygen saturation levels, carbon dioxide levels, and level of sedation. Literature on patients receiving parenteral opioids suggest end-tidal carbon dioxide monitoring is effective in detecting hypercapnia or hypercarbia.
Center for Medicare and Medicaid Services (CMS) ²⁵	Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids, Conditions of Participation – Guidance emphasizes post-operative monitoring of patients receiving IV opioid medications anywhere in the hospital. Best practices include use of electronic monitoring such as continuous pulse oximetry and/or capnography.

outcomes (eg, reductions in reversals, admissions to ICU, rescue calls, code blues, LOS, etc.) and the resultant reductions in the cost of care not only justify the investment made in monitoring those at highest risk but provide a basis of evidence which justifies broader application to all patients. A survey of physicians and nurses revealed that 92% believe that continuous monitoring of patients who are at high risk or in early stages of RC can lead to earlier interventions, preventing further deterioration and 84% agree that RC monitoring can save money by preventing the need for more complex, more costly levels of care (eg, ICU admissions, intubation, ventilation, etc.).³³

Solution on the Horizon?

The PRODIGY trial (<https://clinicaltrials.gov/ct2/show/NCT02811302>) is a multicenter, international, prospective study designed with a primary objective to create and validate a risk prediction tool from continuous respiratory monitoring and patient electronic medical record data that can identify adult patients at risk of respiratory depression episodes when receiving parenteral opioid therapy on the medical and surgical general care floors. The study enrolled approximately 1,500 patients from 16 centers (US-9, EU-4, Asia-3) in 7 different countries allowing potential comparisons across hospitals and geographical regions. The primary endpoints of PRODIGY will be respiratory depression (RD) as detected using ‘blinded’, non-alarming continuous capnography and oximetry monitoring on the GCF, RD being defined by one or more of the following: 1) etCO₂ ≤15 or ≥60 mmHg for ≥3 minutes, 2) RR ≤5 breaths for ≥3 minutes, 3) SpO₂ ≤85% for ≥3 minutes, 4) apnea episode lasting >30 seconds, or 5) any respiratory Opioid-Related Adverse Drug Event (rORADE).^{31,34}

Secondary objectives of PRODIGY will include a comparison of RD risk subjects versus no-risk subjects in terms of incidence of adverse events and interventions, healthcare resource utilization,

and subject mortality at 30 days. The predictive value of etCO₂, RR, SpO₂, and the Integrated Pulmonary Index™ algorithm will be correlated with the occurrence of RD and ORADEs. Data from two-thirds of study participants will be used to derive the risk assessment tool (Derivation Cohort). Data from the remaining third will be used to validate the tool (Internal Validation Cohort).^{31,34}

The recently released ‘PRODIGY: Seeking Answers’ paper is the first publication from the trial discussing the rationale of this study and the methodology being used.³¹ Results from the trial, including primary and secondary objectives, will be published in subsequent papers to follow.

Summary

RC is a common, costly, deadly, and often preventable problem in hospitalized patients receiving opioids and across all hospital environments. Continuous, electronic monitoring of oxygenation and quality of ventilation to aid in early identification and intervention in patients at risk has been identified as one mechanism to improve outcomes. Development of risk prediction modeling could be a significant step forward in understanding which patients would benefit most from prevention strategies, including continuous monitoring.

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Company Achieves Accreditation with ACHC

CAIRE Inc. announced its approval of accreditation status by Accreditation Commission for Health Care (ACHC) for the services of effectively and efficiently delivering quality healthcare oxygen therapy products and services to consumers. "This accreditation marks a major milestone in the life of our brand, and our continued commitment to excellence and quality in service to our customers suffering from Chronic Obstructive Pulmonary Disease, and other serious respiratory diseases," said Dan Van Hise, Vice President of Marketing for Chart's BioMedical Group. Achieving accreditation is a process where healthcare organizations demonstrate compliance with national standards. Accreditation by ACHC reflects an organization's dedication and commitment to meeting standards that facilitate a higher level of performance and patient care. "Members of our regulatory team began months ago identifying and establishing the required processes to meet the ACHC requirements. This achievement is the result of dedicated efforts and collaboration across several departments within the organization. It is a worthy accomplishment that we should be proud of, but most importantly the accreditation ensures we have procedures and processes in place to consistently deliver high quality products and services to our customers," said Neal Maloy, Chart BioMedical Director of Quality and Regulatory. ACHC is a not-for-profit organization that has stood as a symbol of quality and excellence since 1986. ACHC is ISO 9001:2015 certified and has CMS Deeming Authority for Home Health, Hospice and DMEPOS. CAIRE is a globally-recognized brand in oxygen therapy and manufacturer of portable oxygen concentrators, stationary oxygen concentrators, and liquid oxygen therapy systems. Well-known products include the wearable Focus and FreeStyle series, the portable Eclipse 5, and stationary oxygen concentrators including the Companion 5 and Intensity. CAIRE's respiratory Center of Excellence and manufacturing headquarters north of Atlanta is home to its customer and technical service teams, engineering, regulatory, and marketing teams.

Measure Respiratory Signals with Insight

Company Hans Rudolph announced news features for its *SmartLab Instrumentation System* with *Insight* software, a flexible data-acquisition system for use in making measurements of respiratory signals. It is a modular system that can be configured for a variety of measurements. The base module consists of a main system circuit board that can accept up to four sensor modules. It also has an input for a Nonin xPod oximeter and a Masimo IRMA CO₂ concentration sensor. An optional internal oxygen concentration sensor is also available. Digital I/O ports with eight outputs and four inputs can be connected to a valve controller or other device that can accept TTL level digital signals. An optional analog output module is available for retransmitting up to 4 measured or calculated values. In addition to these standard applications, they have recently launched a new ECG Sensors & Module, Lung Compliance and Air Way Resistance Processor upgrade and MRI Compatible Pulse Oximetry & Respiratory Band Sensors and Modules. New features include ECG Modules for both 110V & 230V applications with three leads and upgradable sensors, lung Compliance & Airway Resistance Processor upgrade, and MRI Compatible Pulse Oximetry & Respiratory Band Sensors and Modules. The base unit holds up to 4 sensor modules. Differential pressure sensor modules with full scale ranges from 2 cmH₂O to 350 cmH₂O. Absolute pressure sensor modules for barometric

pressure or altitude compensation. Up to 5 calibration tables for each sensor module. Two RS-232 serial ports for connection to an oximeter and CO₂ sensor. Optional internal oxygen concentration sensor. Internal or external temperature and humidity sensor. Works with all the Hans Rudolph pneumotachs. Calculates tidal volume and several respiratory parameters from the flow and airway pressure signals. Data transmitted over USB or wireless connection. Up to 8 data channels at up to 200 Hz rate.

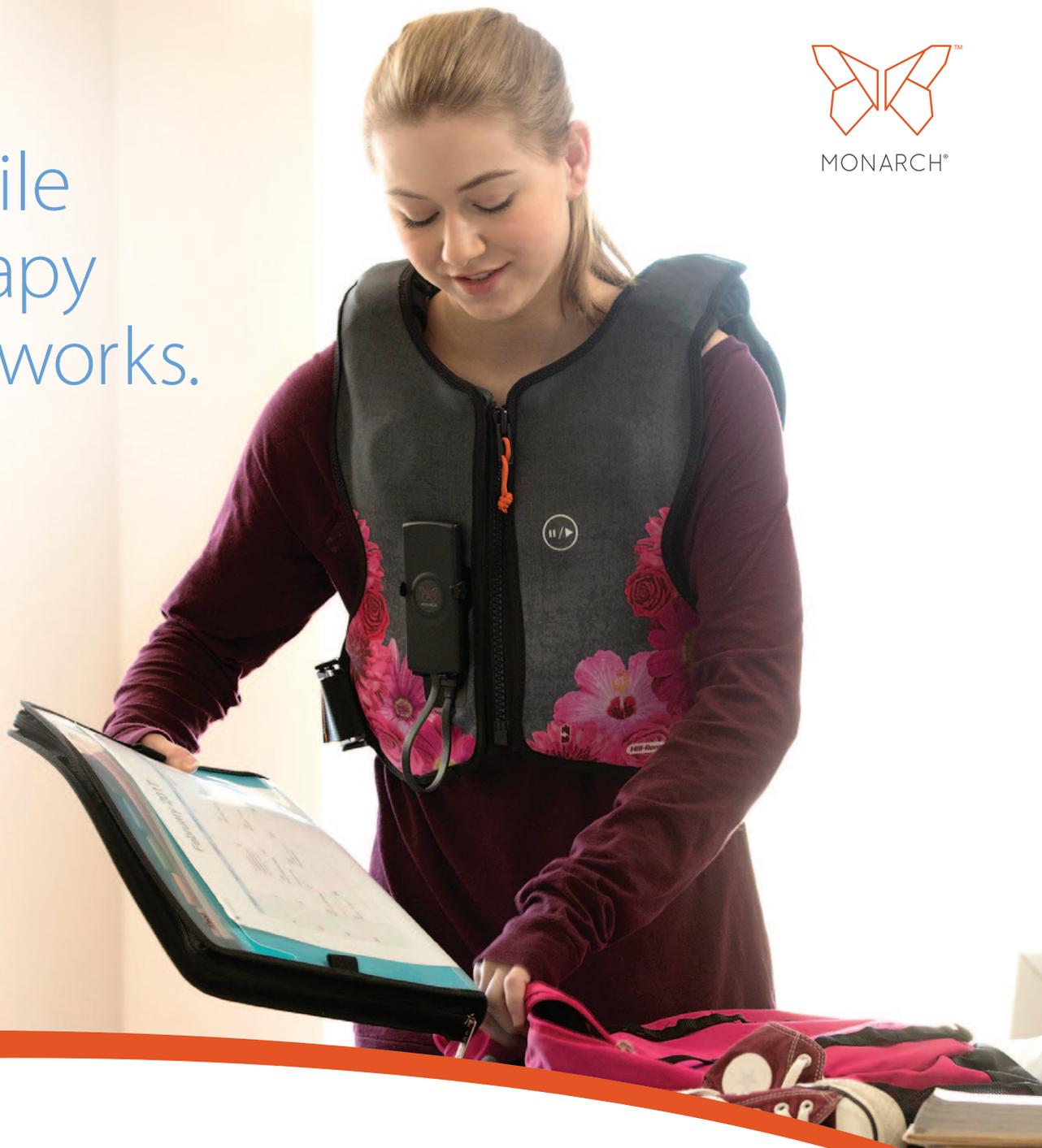
Positive Results for Device

CSA Medical Inc. presented positive results of its feasibility study of the RejuvenAir Metered Cryospray system at the 2018 European Respiratory Society (ERS) Congress in Paris. In an analysis of 30 patients at 6-month follow up, treatment with RejuvenAir resulted in clinically meaningful improvement in Quality of Life, as measured by Saint George's Respiratory Questionnaire (SGRQ) and COPD Assessment Test (CAT). The procedure demonstrated a strong safety profile and was well tolerated. Dirk-Jan Slebos, MD, PhD of the Department of Pulmonary Diseases, at the University Medical Center Groningen, The Netherlands reported that "The RejuvenAir therapy appears to have a beneficial response with a decrease in cough and mucus production even in our patients who had optimized medical management. The overall improvement in breathing resulted in increased physical activity supporting the potential for RejuvenAir to measurably improve quality of life in chronic bronchitis patients." As reported at ERS, RejuvenAir therapy demonstrated strong safety and tolerability profile during the study with minimal procedure related adverse events and serious adverse events. Importantly, there were no pneumothorax or pneumomediastinum events. Patients were able to be discharged from outpatient bronchoscopy suite on day of treatment. On SGRQ, patients treated with RejuvenAir improved by an average of 10.9 points ($p < 0.02$) at 6-month follow-up. According to peer-reviewed literature, an improvement of 4 points on SGRQ is considered to be clinically meaningful. On CAT, patients treated with RejuvenAir improved by an average of 3.4 points ($p < 0.02$) at 6-month follow-up. According to peer-reviewed literature, an improvement of 2 points on CAT is considered to be clinically meaningful. "We are encouraged by these positive safety and feasibility results and we're moving forward with plans to initiate a worldwide pivotal study of RejuvenAir in chronic bronchitis in 2019," said Wendelin Maners, CSA Medical's Chief Commercial Officer, who further stated, "We look forward to advancing this novel therapy toward commercialization to provide relief to the millions of patients suffering from COPD with chronic bronchitis." The Safety and Feasibility Study of RejuvenAir for Treating Chronic Bronchitis Patients (NCT02483637) is a prospective, open label, single arm study of COPD patients with known chronic bronchitis is being conducted at three sites in The Netherlands, United Kingdom, and Canada. The study strongly supports the feasibility of using Liquid Nitrogen Metered Cryospray (MCS) throughout the central airways to ablate inflamed bronchial epithelium allowing non-inflamed tissue to regenerate after treatment. Phase A of the study enrolled 11 patients and treated a single lobe to assess safety, feasibility and histologic/immunologic response. In Phase B of the study, Phase A patients had their remaining lobes treated and 24 additional patients were enrolled and treated. All patients have received complete treatment of both lungs and they are being periodically followed for safety and physiologic response of their underlying chronic bronchitis to this novel treatment. Primary endpoints include, 1) adverse and serious adverse

events and ability to complete all three treatments, and 2) mean change from baseline total SGRQ score. Secondary endpoints include CAT, 6-minute walk test, spirometry testing, and other objective pulmonary function tests and patient reported outcome instruments. Exacerbation rate was measured as an exploratory endpoint. Chronic Bronchitis is the largest disease subset of Chronic Obstructive Pulmonary Disease (COPD). Bronchitis is inflammation of the bronchial airways. A chronic bronchitis diagnosis is defined by cough with productive sputum of three months duration for two consecutive years. In addition to a chronic inflammation, cough and increased production of mucus, chronic bronchitis may or may not present with obstruction/partially blocked airways due to swelling and excess mucus in the bronchi, or shortness of breath (dyspnea). In the United States, there are an estimated 12.7-14.7 million people with COPD, and in 2011 approximately 10 million people sought medical attention for chronic bronchitis, a subset of COPD. Approximately 700,000 people are hospitalized for symptoms/exacerbations of chronic bronchitis every year. In Europe, there are approximately 23 million people with COPD. There are approximately 1.5 million hospitalizations per year for COPD. The RejuvenAir Metered Cryospray System is designed to spray liquid nitrogen at -196°C in a circumferential pattern within the airway. It is anticipated that the rapid freezing of the epithelial layer of the airway walls will destroy the mucus-producing goblet cells while preserving the extracellular matrix, thereby enabling the regrowth of healthy cells. The RejuvenAir System is currently under clinical investigation and is not commercially available.



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